CADTH

CADTH COMMON DRUG REVIEW

Patient Input

cabotegravir-rilpivirine and cabotegravir sodium (TBC)

(ViiV Healthcare ULC)

Indication: HIV-1 infection

CADTH received patient input from:

- ACT, EMHC, MAX Ottawa and CBRC (Joint Submission)
- AIDS Committee of Ottawa (ACO)
- Alliance for South Asian AIDS Prevention (ASAAP)
- Canadian Treatment Action Council (CTAC)
- Realize

September 10, 2019

PatiPatient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Cabotegravir-rilpivirine cabotegravir sodium
Name of the Patient Group	Gay, bisexual and queer men
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

This is a joint submission from ACT in Toronto, MAX in Ottawa, EMHC in Edmonton and CBRC (a national organization based in Vancouver). We are four non-profits working in the sectors of gay and queer men's health, with a focus on HIV prevention. Together our organizations have significant reach into the populations of gay, bi and queer men.

ACT is a community-based non-profit organization that provides a range of free, confidential services to men women and uyoung people living with HIV in Toronto, as well as HIV and STI education and prevention focused on gay men, women and young people at increased risk for HIV in Toronto. ACT also offers programs and services that address the sexual health, mental health and community health needs of diverse groups of gay, bisexual and other men who have sex with men. Our website is www.actoronto.org

EMHC is a grassroots health organization run by and for gay, bi, queer, and trans men and two spirit people (GBTQ2S+). Works toward health equity for GBTQ2S+ through community education, capacity-building, and support; provider training; and community based research. Our website is https://www.yegmenshealth.ca/

MAX Ottawa is a community-based organization that focuses on maximising the health and wellness of gay, bisexual, Two-Spirit, queer, and other guys who are into guys, both cis and trans (GBT2Q), in the Ottawa region. We reach guys into guys where they meet and socialize, raising awareness, providing prevention and education materials, and getting them connected to information and resources. MAX offers individual, group, and community support and education services by and for guys into guys in the Ottawa region; and we work with the healthcare providers that serve them. Our website is http://maxottawa.ca/en/

Community-Based Research Centre (CBRC) promotes the health of gay men through research and intervention development. We are inclusive of bisexual and queer men (cis and trans) and Two Spirit people.CBRC's core pillars - community-led research, knowledge exchange, network building, and leadership development - position the organization as a thought leader, transforming ideas into actions that make a difference in our communities. CBRC was incorporated in 1999 and is a non-profit charitable organization. Our main office is located in Vancouver, British Columbia, and we also have satellite offices located in Edmonton, Toronto, and Halifax. Our website is www.cbrc.net

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

We are a group of leading health and AIDS service organizations with more than 50 years of collective experience serving gay, bisexual, trans, queer and 2 Spirit (GBTQ2S+) men and other communities affected by HIV. Input has been provided by staff from all of our organizations. These staff members speak from personal experience as GBTQ2S+ community members, intimate knowledge of GBTQ2S+ health research, and a great deal of expertise and experience working in GBTQ2S+ health and expertise. In addition, several of us have spoken with staff in our agencies living with HIV, as well as service users to provide insight into our responses.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

While we have made many strides in improving the quality of life for people living with HIV, these benefits are not experienced equitable by all living with the virus. Those who experienced increased vulnerability and marginalization, whether due to socioeconomic or immigration status, continue to experience challenges in accessing treatment, remaining in care, and achieving and sustaining a suppressed viral load. Additionally, despite increasing knowledge of HIV being a chronic, manageable condition, misinformation and continued discriminatory policy such as the overcriminalization of HIV non-disclosure, continue to fuel HIV stigma. People living with HIV, therefore, experience significant stigma - and at times physical danger - because of their HIV status. Therefore, any enhancements in treatment which can lessen the daily stigma faced by people living with HIV should be made accessible to all people living with HIV, not just those with high disposable incomes or desirable private insurance plans. In addition, we know that some groups, particularly youth, struggle with adherence to daily medications, similarly any enhancements in treatment administration/delivery should be considered important tools for achieving a suppressed viral load.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

For some (particularly youth) taking a daily pill is a significant barrier to their ability to access and remain on treatment; whether that be due to a lack of stable housing, mental illness, or HIV stigma and intimate partner violence. It is still incumbent on us to find HIV treatment options which effectively address the unique needs experienced by these individuals. In these situations, adhering to a daily pill may not be feasible. However, if these individuals were able to access monthly (or even less frequent) injections, at an individual level, it could

help address those barriers. At a public health level, it could help to fill critical gaps in the continuum of care as it relates to linkage and adherence to HIV treatment and, subsequently, achieving a suppressed viral load.

Injectables are also beneficial for guys seeking privacy and discretion with their medication. For example, we were shared with an experience of a guy living with HIV and having an ex-roommate who was a “germophobe”. This person had made negative comments about HIV. The guy living with HIV was constantly “watching his back” and hoping the roommate would not find any evidence of his daily HIV medications. Having an option of a monthly injectable for HIV treatment would remove that anxiety caused from wanting to “hide”.

The need for discretion also applies to those who travel, whereas certain countries forbid travel from those infected with HIV, or may use HIV meds as a proxy for other ‘illegal’ behaviour, such as homosexuality or drug use. Fear of partner violence or employment discrimination are other important reasons persons living with HIV, or those trying to prevent HIV, may need more discrete, less frequent treatment options.

5. Improved Outcomes

CADTH is interested in patients’ views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Reduced stigma. Reduced burden of taking a daily pill. Improved adherence/viral suppression for those whose lives are not conducive to daily pill access/adherence.

It is common to see migration to cities among gay, bisexual and queer men. Provincial boundaries have an impact on this migration and sometimes it takes time for people living with HIV to get a new doctor and insurance in the new place. This is particularly a challenge for HIV positive folks. Having a long acting HIV treatment option would help overcome this. The same challenge is faced when changing jobs. Sometimes it takes a few months for benefits to kick-in and people living with HIV that cannot afford the drugs have to stop taking them during the transition period. Long-acting injectables would help alleviate this challenge.

People living with HIV who are living in precarious housing conditions would also benefit from long-acting injectables.

Some guys older than 50 years old living with HIV who are long term survivors, have reported different levels of dementia: taking drugs everyday becomes harder for them, so having the option of an injectable would ensure adherence to medication.

As described above, injectables are also beneficial for guys seeking privacy and discretion with their medication. In this sense, this option helps to prevent potential violence from romantic or sexual partners who could react negatively when finding HIV treatment.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

None of the individuals who are contributing to this patient input submission have had the opportunity to access this drug. However, a staff member of one of the organizations attended a panel with participants of the injectables trial. He heard them say, in summary, that the drug helped to reduce stigma and anxiety.

In addition, some of our service users living with HIV have chatted to other guys who have been in ARV injectable trials. They have reported to us that they hear from those at the trials being happier with the long acting option and report looking forward to it.

Overall, we know that the more options available, the more likely people are to adhere to their medications. We've seen new technologies bring new interest to HIV prevention and treatment. Injectables would be seen as an exciting new HIV prevention and treatment options for a population significantly impacted by HIV.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

Not applicable.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

One of the concerns discussed is the lack of service providers. When folks are not part of a trial how will the health system guarantee the service delivery by properly trained providers? Another thing to keep in mind is to ensure that this option would not be used to coerce people living with HIV into medication. We would encourage regulation/ guidelines to ensure self-determination by the patient, in consultation with the service providers.

A question that arose during the discussion is cost. Will folks without public or private health plans be able to benefit from this new technology if they would wish to access it but can't afford it? It would be important to ensure that marginalized folks can access it since, as discussed above,they would be some of the populations that would most benefit from an injectable form of HIV treatment.

Another thing to consider is cultural history with injectable drugs in certain communities (i.e.: Indigenous).

Another recommendation that was discussed is the benefit of potentially having nurse practitioners prescribing this drug. From a community health perspective this would mean more prescribers which would help for communities with less physicians to access it (i.e.: rural, North, precarious housing status).

In conclusion, injectable ARV should help and work for the benefit of the more marginalized living with HIV, and not against them.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
ViiV Healthcare Canada (CBRC)			X	
ViiV Healthcare Canada (ACT)			X	
ViiV Healthcare Canada (EMHC)			X	
ViiV Healthcare Canada (MAX Ottawa)			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: John Maxwell
Position: Executive Director
Patient Group: ACT
Date: 09/09/2019

Name: Roberto Ortiz
Position: Executive Director
Patient Group: MAX Ottawa
Date: 09/09/2019

Name: Brook Biggin
Position: Founding Member
Patient Group: EMHC
Date: 09/09/2019

Name: Jody Jollimore
Position: Executive Director
Patient Group: Community-Based Research Centre
Date: 09/09/2019

September 9, 2019

Re: Community Feedback on Long-Acting Injectable HIV Regimen

Dear CADTH:

It is with great pleasure that I write this letter, on behalf of the AIDS Committee of Ottawa (ACO), to provide community feedback on the long-acting injectable HIV regimen.

ACO is a community agency whose mission is to provide support, prevention, education and outreach services from an integrated anti-racism/anti-oppression social justice framework that promotes the holistic well-being of those living with, affected by, and at risk of HIV/AIDS in Ottawa. ACO has served the national capital region for 35 years and is the leader in the community-based response to HIV/AIDS in Ottawa. Some of the priority populations that ACO serves includes GBMSM, ACB, Indigenous and the Drug Using communities.

Our staff and volunteers have had informal conversations and discussions with our clients at our drop-in centre regarding their thoughts and opinions on a long-acting injectable HIV regimen. The feedback that we have received from our community members is that a once a month injectable is a viable option and would go a long way in reducing stigma and other barriers. Some people said that they would not have to hide their HIV pills from their family and friends, in cases where people have not disclosed their HIV status. Also, people mentioned that it would help in with adherence to their medication as they would not forget to take their pills. Some concerns were around the cost of a monthly injectable and if it would be affordable and covered by insurance, as well as any potential side effects of the medication. All in all, what our community members are look for in an injectable option is something that is accessible and affordable, something that helps with adherence and reduces stigma associated with one's HIV status, and something with minimal side effects.

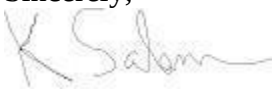
THE AIDS COMMITTEE OF OTTAWA - LE COMITÉ DU SIDA D'OTTAWA
19 Main St, Ottawa, Ontario K1S 1A9 - Tel.(613) 238-5014 - Fax/Téléc.(613) 238-3425
The Living Room/Le Vivoir - Tel. (613) 563-0851 - 1-800-461-2182 (Ontario/Québec only/seulement)
www.aco-cso.ca

Member of * Ontario AIDS Network *
Charitable Registration Number 10807 0749 RR0001

Last but not least, on behalf of ACO, I would like to declare that we do not have any conflict of interest regarding this matter.

If you have any questions or require more information, please do not hesitate to contact me.

Sincerely,



Khaled Salam
Executive Director
AIDS Committee of Ottawa
(613) 238-5014 ext. 234
Khaled@aco-cso.ca

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**cabotegravir/rilpivirine and cabotegravir sodium / HIV-1 Infection**
Name of the Patient Group	**The Alliance for South Asian AIDS Prevention (ASAAP)**
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

The Alliance for South Asian AIDS Prevention (ASAAP) provides HIV/AIDS, sexual health and support services for South Asian communities in the Greater Toronto Area. Our services are offered in English, Tamil, Hindi, Urdu, Gujarati, Bengali, Arabic, Farsi and Nepali. Our programs and services are delivered in culturally appropriate ways while simultaneously challenging the discomfort many have in talking about sexuality and sexual health. We acknowledge the many social determinants of health and our work often overlaps with issues of racism, gender equity, housing, violence, mental health and employment.

Website**:** www.asaap.ca

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

We work with 75 individuals of South Asian and Middle Eastern heritage who are living with HIV and approximately 50 individuals who are affected by HIV (have a partner who is HIV positive or from a high-risk group). Over the last 6 months, we have had 6 new referrals of individuals who

have been newly diagnosed. We engage our clients through monthly group support and one-on-one sessions, as well as through a project advisory body called the Support Program Advisory Committee (SPAC), made up of our clients but have a keen interest in the delivery of services and policies. A regular topic of discussion during interactions with our clients is adherence to medication.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Please refer to question 4 as the experience of our patients are interconnected.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

Sadly, 30 years into the epidemic, individuals living with and affected by HIV still face a stigma in the community and have internalized the stigma. As a coping mechanism - many of our clients have turned to drugs or alcohol and do not adhere to their medication or experience significant side-effects as a result of the substances and not the medication. They often have to switch medications that lead to severe side-effects, again because their bodies are not able to metabolize the medication. Still others, do not take their medications for fear of a family member, roommate, friend, coworkers asking questions about them taking medications and what it is for. They also fear that people may discover their HIV status via the medication they are taking. As a result, they often miss dosses or transfer medication into different bottles and do not label them – leading to issues around medication adherence. The shame, guilt and stigma that surrounds an HIV diagnosis is not a superficial feeling, it is rooted in culture and communities as sex and sexuality are still taboo topics. So, advice from us to clients are "tell them you have cancer or another illness so that people do not ask too many questions of you during taking your medication and will support you to medical appointments etc." It is unfortunate, but if it will help individuals adhere to medication – then that is a strategy to use. We also inform them of legal responsibilities.

For individuals like our clients, having a long lasting injectable that is affordable and covered under the formulary will allow for greater medication adherence and can be done outside of the

home during regular doctor /clinical visits. They can do so free of the shame and guilt experienced when taking a pill everyday and do not have to miss doses because a family member is around.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Similar to the response in question number 4 – stigma, shame and guilt are driving factors in medication adherence or lack of. We find that the number one reason for individuals to stop treatment is around the frequency and having the medication in the house where other members of the family or household do not know their HIV status. Secondly, those who struggle with addictions (drugs and or alcohol) do not adhere as they forget or fear drug interactions. Thirdly, many of our clients are living on social assistance and can not afford healthy or nutritious food or even unhealthy food as funds go to pay for housing and utilities. Food banks are great, but for those who have no ID or issues with Food Banks – they are unable to access foods.

In understanding these issues, we hope you would consider the following:

1) Medication/treatments that are longer lasting and can be used intermittently with the same effect (which this medication does)
2) Medication/treatment that can be taken without food for those who are precariously housed, underemployed etc. so that individuals choose not to take their meds if they have no food
3) Medication/treatment that does not have to be taken daily to remind an individual that they are living with HIV and or alert members of their families/household they have HIV.
4) Medication/treatment that can be used by someone who uses drugs or alcohol so that they don't have to choose between one or the other, but be able to do both. We as health service organizations can then employ harm reduction principles to help an individual facilitate adherence to treatment.
5) Affordability and opportunities where drug companies can cover some costs associated with prescription filling etc as individuals don't have to struggle with paying to have prescriptions filled and do not fill their prescriptions and therefore do not adhere to treatment.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? No one has had access to treatment within our centre.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

Not Applicable

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.
    a. No, we used our current client community for information

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.
    a. No, we did not

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
ViiV – for our client care program as we starting up with the Middle Eastern Programming – which is new for our program. The folks we spoke to are South Asian identified.			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Haran Vijayanathan
Position: Executive Director
Patient Group: South Asian community
Date: Oct 1, 2019

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**cabotegravir-rilpivirine cabotegravir sodium, HIV Infection**
Name of the Patient Group	**Canadian Treatment Action Council (CTAC)**
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

The Canadian Treatment Action Council (CTAC) is Canada's national non-governmental organization addressing access to treatment, care and support for people living with HIV and hepatitis C. CTAC's organizational goals are to meaningfully engage community members, service providers, policymakers and other relevant stakeholders to identify, develop, and implement policy and program solutions. CTAC understands that treatment access should be considered in its holistic form, encompassing the range of treatment, care and support needs required to reach the most successful treatment experience possible for people living with HIV and/or viral hepatitis co-infection. Full CTAC membership is reserved for: a) individual people living with HIV (including HCV co-infection); b) organizations, groups or projects with a substantial HIV mandate (including HCV co-infection). Associate CTAC membership is open to any individual, organization, group or project that supports CTAC's mandate and objectives

Website: http://www.ctac.ca/

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

On August 28, 2019, CTAC delivered a patient input consultation workshop in Toronto that provided an overview of the Common Drug Review patient input process and key findings from the cabotegravir/rilpivirine clinical trials. Amanda Fletcher (Director of Policy, Research, and Development at CTAC) delivered the consultation workshop. People living with HIV were invited to participate in the workshop. We also recognize that CDR patient input submissions are much stronger if the voice of people who have had (or believe themselves to have had) experience with the new therapy under consideration are included. As such, we attempted to invite those to the workshop who had experience with any of the components within this 2-drug combination, or the new combination itself. CTAC also administered a web-based survey that was advertised on CTAC's website, publicized on social media, and emailed to CTAC members and partners. The survey was made available from Tuesday August 20, 2019 to Wednesday September 4, 2019.

Seven individuals attended the workshop, and fifteen individuals completed the online survey. In total, CTAC has compiled data from all twenty-two individuals. All of the respondents identified themselves as HIV-positive. Thirteen individuals identified as male. Seven individuals identified as female. One individual identified as bisexual. One individual identified as non-binary. CTAC had a wide age range of individuals that participated in either the workshop, or the online survey. One participant was under 20. Six participants were in their 20's. Two participants were in their 40's. Eleven participants were in their 50's, and two participants were in their 60's. All of the participants are currently on treatment for HIV. The number of years in treatment varied from less than 1 year (8 months) to approx. 35 years. In addition to the results of the survey and workshop, survey data collected for a patient submission on dolutegravir, and dolutegravir rilpivirine have been used to inform and support this patient submission.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

HIV is a serious, life-threatening illness that threatens the immune system. Over time, if left untreated, HIV can compromise a person's immune system to the point that the body may no longer be able to fight off opportunistic infections. As of 2016, 63,110 Canadians are living with HIV (Public Health Agency of Canada). Access, administration of and adherence to highly active antiretroviral treatment (HAART) can control the progression of a person's HIV. In most cases, people taking HAART achieve an undetectable viral load (or viral suppression), the point at which there is so little HIV in the bloodstream (<50 copies/mL) that it cannot be detected by conventional medical technologies. Viral suppression is linked to marked improvement in long-term health outcomes and drastically reduces the possibility of transmitting HIV to sexual partners.

While achieving and maintaining an undetectable viral load via HAART means HIV-positive people can live long lives and manage their HIV as a chronic illness, people living with HIV experience the effects of "accelerated aging". According to Centers for Disease Control and Prevention (CDC) HIV/AIDS surveillance data from 1985 to 2010, people with HIV are living longer, where more than 35% are aged 50 or older. As people living with HIV are aging, they are also more susceptible to inflammation and non-infectious co-morbidities, including bone fractures and renal failure, at earlier ages. From the

literature, co-morbidities, such as kidney, liver, and cardiovascular disease, are more common in people living with HIV than the general population. Increased risk of experiencing co-morbidities is due to several risk factors, including co-infection and antiretroviral treatments themselves. In a study, people living with HIV between ages 41-50 are 16 times more likely than the general population to develop renal failure, and 46 times more likely to develop renal failure when over 60 years of age. When considering bone fracture risk, HIV+ people between the ages 40-60 are 12-16 times more at risk than those uninfected with HIV (Guaraldi G, et al. Outcomes Res. 2013 Sep 23;5:481-8).

As a chronic illness, HIV can present a number of complications, and these can vary from day to day and from patient to patient. At CTAC, we know that many people living with HIV experience negative mental health outcomes, either as side effects from treatment, or from facing stigma, discrimination, and related stress. One participant explained how mental health supports were lacking and that they were not prepared, psychologically, for living with HIV when transitioning into adulthood. This greatly affected their ability to adhere to their medication, *"I did not have enough psychological support to help adhere to treatment. Because I had been taking it as a child, I wasn't really prepared or supported in taking it as an adult and being consistent. Especially after both my parents died by the time I was 19"*. A participant from our dolutegravir rilpivirine survey noted that there are also issues with stigma in the medical community, *"Local doctors feel ill-equipped to treat HIV due to inexperience because of low patient caseloads with the condition. Stigma also play into it I think. Unless they're familiar, doctors still see HIV as something more difficult to live with than it actually is."* Another participant from our dolutegravir rilpivirine survey discussed the challenge of managing HIV while residing in a rural area, *"I live in a rural area and have to travel about 100 km. each way for my doctor's appointments. I only see my doctor about every six months. Obviously if I had to travel that far more often it would be a challenge. For those who don't have the support of family this could definitely be an obstacle."*

In 2011, the Canadian AIDS Society released a study that estimated a $1.3 million total economic loss per Canadian living with HIV (analyzing statistics current through 2008). This includes a $670,000 average loss per HIV-positive person in labour productivity and a $380,000 average loss in quality of life. As a result of being on HIV treatment, many participants described noticeable improvements in their quality of life and ability to engage in daily activities. Discussing the overall impact of treatment on their life, one participant stated, "*HIV treatment has allowed me to keep working and maintaining a social life, or I would have been too sick otherwise."* When asked whether treatment had improved their quality of life, another participant answered, "*Absolutely! I no longer feel tired all the time. Also, slowly but surely, more people are aware of what being undetectable truly means. That is as a direct result of the medications!"*

Many people living with HIV experience intersecting vulnerabilities conditioned by the social determinants of health – the social and structural conditions in which people are born, live, work and age, shaped by the distribution of money, power and resources at the local, national and international levels. The following stories from respondents reflect the substantial impact that the social determinants of health, particularly employment and the accessing of public health benefits, have had on managing their HIV:

"Cost has at times been a factor; even though I have private insurance, I must pay upfront and then get reimbursed (takes from 2-4 weeks). Co-pay is 10%, some of which is covered by Trillium Drug Plan, but again cannot seek reimbursement until after private insurance has paid their share, and then it still takes several weeks to process."

"My challenges are not treatment related, but more about how I am treated because I work periodically and I access Trillium. The Trillium plan is a barrier for people who work part time or periodically. Aids organizations and the government itself often assume that people will go onto ODSP or have private drug plans." [respondent from dolutegravir rilpivirine survey]

As a result, HIV is a complicated illness that requires treatment options that can be tailored to individual needs, delivered in innovative capacities that bolster access to treatment, care and support, such as treatment outreach programs, low-threshold health care services, adherence programs and social supports.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

HIV is a complex illness and people living with HIV have varying responses to treatments that are currently available. Most people living with HIV are able to work with their physicians to find a therapeutic regimen that achieves viral suppression. However, some people living with HIV are not able to achieve viral suppression, despite trying multiple treatment regimens. Additionally, treatment adherence (taking medication when prescribed, as prescribed) is necessary for treatment to be effective; non-adherence can lead to drug class resistance, requiring the adoption of a new regimen selected from fewer available treatment options. As a result, having the maximum possible treatment options available is of clinical importance.

Findings from our workshop and online survey indicate that, of the twenty-two respondents who identified as living with HIV, all are currently on treatment for their HIV. Their length of time on their current therapies varied from approximately 2 months to 12 years for all of the respondents, and minor changes have had to be made due to other health problems, or resistances that have developed. Considering our workshop and survey populations were primarily made up of long-term survivors (individuals who have been living with HIV for up to 35 years), this result demonstrates that there is relative stability with the new generation of HIV medications, but individuals living with HIV will change their treatment regimen after advancements in medications, or due to other health complications. This emphasizes the significant need for the availability of several HIV treatments.

All of the participants that came to the workshop, and completed the cabotegravir/rilpivirine online survey, indicated current or past use of regimens containing darunavir, dolutegravir, emtricitabine, rilpivirine, lamivudine, and/or tenofovir. Treatments ran the gamut from Viread to Intelence, Triumeq, Genvoya, Norvir, and/or Biktarvy with different combinations of the above being utilized. Participants noted that their current treatment was effective at suppressing their viral load, but that they had experienced side effects as a result of previous treatments that they had received when they were first diagnosed. One participant noted that, *"I've been on treatments in the past that resulted in me having severe mood swings, and I wasn't able to sleep at all. I'm very concerned about the side effects of new medications, especially because I'm older and have a lot of comorbidities to consider."*

In the dolutegravir consultations, participants highlighted a number of areas where they had, or could benefit from, caregiver support. They all noted substantial impact on caregivers looking after patients living with HIV. One participant highlighted that the challenges his/her spouse faces in providing support is surrounding disclosure. According to the participant, "*hiding from friends and some of our family members that I am HIV positive*" has been extremely difficult and hindered the ability to acquire a social safety net. Others noted service provider knowledge, staff time, funding, transportation and other associated costs as barriers to providing support and its impact on treatment adherence, mental health and other determinants of health. One participant noted, "*There are a lot of challenges associated with lack of knowledge about services and how to access them. Such as dental care, legal aid (writing of wills, living wills, how to access disability benefits etc...)"* In addition, more than one participant noted that difficulties understanding stigma and its impact, and navigating HIV-specific social services and institutional systems, including disability, insurance and mortgage, have presented specific challenges.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Cabotegravir/rilpivirine can be administered in two ways: 1) as a once-daily, oral, fixed dose combination; or 2) a monthly, long-acting IM injection. Of the 2 drugs in this combination, Rilpivirine (EDURANT) is already on the Canadian market. The clinical trials for cabotegravir/rilpivirine have shown that switching to this 2DR combination (either oral or oral + injection) is associated with high HIV suppression rates, has a low potential for drug-drug interactions, and the potential for less long-term drug toxicity. Also, for those living with HIV, long-acting injectables created using extended-release drug formulations present a possible alternative to taking medication on a daily basis. All of these benefits were considered important for individuals managing lifetime use of HIV antiviral treatment. Many of the participants expressed interest in a drug with a new chemical composition that also offers the potential of only having to be taken as an injection once a month. One participant noted that, *"I'm interested in the injectable form of this new medication. I'm really bad at taking medications, so this injection sounds pretty good."* However other participants, like this participant from our dolutegravir rilpivirine survey noted that, *"I don't see replacing the "devil" I know with the "devil" I don't know - at least on a personal basis. If I had to make changes - and that time could come since I've been on the present regime for quite some time."*

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and

families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

None of the participants within the workshop, or who completed the online survey, had experience with the combination drug cabotegravir/rilpivirine.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

8. Biosimilar

If the drug in review is a biosimilar (also known as a subsequent entry biologic), please outline any expectations or concerns held by patients, caregivers, and families about the biosimilar. If the biosimilar was less expensive than the brand name drug, what would the impact be for patients, caregivers, and families?

9. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

CTAC continues to acknowledge and appreciate CADTH and CDEC suggestions as to how to improve patient input submissions, and is motivated to discuss revisions, reform, and refinements to the patient input process that can better represent the patient voice as well as improve the work of not only submitting organizations, but also the CDR as a whole.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

   CTAC did not receive help from outside our patient group to complete this submission

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

   CTAC did not receive help from outside our patient group to collect or analyze data used in this submission

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
ViiV Healthcare			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Amanda Fletcher
Position: Director of Policy, Research, and Development
Patient Group: CTAC
Date: September 09, 2019

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**cabotegravir/rilpivirine and cabotegravir sodium / HIV-1 Infection**
Name of the Patient Group	***Realize***
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

Realize is the leading national, charitable, organization working to improve the health and well-being of people living with HIV and other episodic disabilities, across the lifespan, through integrated research, education, policy and practice (www.realizecanada.org).

Formed in 1998, ***Realize*** (formerly the Canadian Working Group on HIV and Rehabilitation) promotes innovation and excellence in rehabilitation in the context of HIV and other chronic and potentially episodic conditions. In order to promote a comprehensive approach, ***Realize*** is multi-sectoral and multi-disciplinary in its membership and activities.

Realize members come from across Canada, as well as internationally, and include people living with HIV and other chronic conditions, members of community-based HIV and disability organizations, national associations of health professionals, government agencies, private businesses, and the employment sector. Members elect a nine-person Board of Directors to guide the organization.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

The data was gathered via the sharing of personal experiences by national members of ***Realize*** who are living with HIV. The stories were gathered over the course of the last 3 months.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Many people living with HIV (PLWHIV) in Canada are now living into older age as a result of powerful antiretroviral therapy regimens introduced in the mid-1990s, as well as the most recent line of treatment that is even more tolerable and accompanied by vastly fewer and less intense side effects. With treatment, care and support, HIV is experienced as many other chronic illnesses are:

- **Episodically -** Periods of good health and physical, mental and social functioning may be interrupted unexpectedly by illness. This can impact work force participation by PLWHIV, affecting their sense of identity, financial security and access to health insurance.
- **Concurrently** - The risk of developing certain comorbidities is exacerbated by HIV, its treatments and/or the social determinants of health.
- **With Little Support -** Stigma related to invisible disability may strain relationships and result in isolation.

PLWHIV also experience unique challenges which marginalize them. They commonly experience stigma and/or discrimination on the basis of their HIV status, which can compromise their social support and decrease their access to health services. Many also experience intersecting forms of stigma, including homophobia, trans-phobia, ageism, racism, and classism. Mental health issues are also highly prevalent among PLWHIV and the uncertainty of living with a chronic illness is further exacerbated, for many, by poor social determinants of health including precarious housing, income and relationships.

4. Experiences With Currently Available Treatments

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Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

As a result of continuous improvements in HIV treatment, many of the side effects that were common with the treatments available early in the epidemic have been eliminated or at least minimized. Despite the leaps and bounds made by science through these improvements in the treatment of HIV, many PLWHIV still continue to experience changes and problems in their body as a result of the drugs they are taking to treat HIV and, in some cases, as a result of the virus itself.

Due to the critical important of adherence as it relates to viral suppression, for many PLWHIV the issue of 'medication fatigue' is a real challenge. Having to take medication every day – and depending on which it could be with or without food e.g. Atripla [taken on an empty stomach], or Prezcobix [which must be taken with food] – for the rest of your life can take a mental toll and, by extension, impact adherence.

Additionally, out-of-pocket costs such as inadequate drug coverage, pharmacy dispensing fees, and clinic travel costs may affect treatment adherence and related health outcomes among people living with HIV.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

The most commonly desired improvement envisioned by PLWHIV is fewer side effects from their HIV medication. This would directly impact their social inclusion by lessening the disruptions in their activities of daily living and by extension, their social participation and inclusion.

A close second would be the possibility of viral load testing being needed every few years, rather than several times a year or even once per year for some people. The ideal would be to be able to test one's viral load the way that someone living with diabetes tests their blood sugar range.

All of the above would also lead to greater destigmatizing of HIV and lend to its credence as a complex chronic condition.

6. Experience With Drug Under Review

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The patients who shared their stories experienced less side effects than their previous drug regimens. This allowed them to be more socially engaged and increased their social participation, both in the workplace (thereby increasing their potential for employment retention), as well in their private lives (thereby allowing them to feel less isolated from their social peers).

They also shared that having an injectable option for their medication, as well as the reduced burden of side effects improved their self-esteem.

7. Companion Diagnostic Test

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Not Relevant

8. Anything Else?

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No

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
ViiV Healthcare			☑	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: **Tammy C. Yates**
Position: **Executive Director**
Patient Group: ***Realize***
Date: **September 10th 2019**