CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

Cabotegravir (Apretude)

(ViiV Healthcare ULC)

Indication: For at-risk adults and adolescents aged 12 years and older and weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection.

February 12, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the views of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions received.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

Patient Group Input

Patient Input

Name of Drug: Cabotegravir-rilpivirine cabotegravir sodium “TBC (cabotegravir)”

Indication: HIV-1 Infection

Name of Patient Group: Africans in Partnership Against AIDS (APAA)

Author of Submission: Fanta Ongoiba, Executive Director

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website

APAA is a non-profit AIDS Service Organization (ASO) located in downtown Toronto . Our mission is to improve the quality of lives of people living with HIV in Canada. We primarily serve persons from the African Canadian Black (ACB) communities in a linguistically and culturally appropriate manner . APAA has various programs including support, prevention, Volunteer, community Development, Heterosexual men’s POZ group, Research, Youth living with HIV support program.

Here is the website for our organization: www.apaa.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.

APAA will be collecting information and feedback from staff members and long term clients on a regular basis. Clients give their input both verbally and in writing in a form of survey, evaluation questionnaire, focus group discussions, regular client meeting. They share their lived experience and mentor each other through which the organization gets information around access to treatment and possible gaps around it .

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?

African Caribbean Black (ACB) people are disproportionately affected by HIV in Canada constituting more than 25 % of new infections in Canada while they only making 3% of Canada’s population. They continue to face HIV related stigma and discrimination. The stigma often leads to isolation and fear of disclosure.

In addition, cultural and linguistic barriers deter ACB people living with HIV from accessing treatment and or advanced / new treatment. Barriers such as limited access to healthcare facilities, financial constraints, and discrimination within healthcare settings can impact the quality of care received.

The experiences of African-Caribbean Black individuals with HIV are shaped by intersectionality, considering factors such as gender, sexual orientation, and socio-economic status. For example, Black women may face unique challenges related to HIV, and those who identify as LGBTQ+ may encounter additional stigma and discrimination.

African -Caribbean Black communities may experience higher rates of HIV compared to some other populations. Factors such as poverty, lack of education, and limited access to preventive measures may contribute to increased vulnerability.

Consequently, challenges such as side effects, pill burden, and the impact of daily medication on lifestyle can affect treatment adherence.

Advances in HIV treatment have significantly improved the prognosis for individuals living with the virus. However, disparities in access to these treatments can still exist, affecting the overall health outcomes of ACB people with HIV.

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).

<ACB people living with HIV that are accessing services at APAA as well as staff members have mentioned the following as advantages of the long term injectable treatment

- Increased privacy: The injectable will reduce the concerns of ACB patients from being seen by others while taking their pills which often lead to stigma and isolation. For some of them who are living in shared accommodations such as shelters taking pills sometimes is precarious as it leads to unwanted disclosure. People will see their pill containers and might find out about their status.

- Decreased risk of treatment interruptions when they travel

- Increased adherence to treatment Some clients face barriers in taking pills every day due to other underling issues .

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?

-Improved health outcomes such as reduced co infections

- Sustained viral suppression

- Increased level of comfort in the 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? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

Some of our staff members attended workshops about long term injectable . Other than this, we haven't come across a client who reported to us that they are formally participating in any of the trials for this drug

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 favorable 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?

APAA is in full support of this drug as it will be helpful in addressing the privacy and stigma issues faced by ACB patients . This will enhance treatment adherence among our clients that have been struggling to maintain daily pill uptake.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, 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.

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

N/A

No

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

List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000

VIVEE		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: Fanta Ongoiba

Position: Executive Director

Patient Group: Africans in Partnership Against AIDS (APAA)

Date February 1,2024

Name of Drug: cabotegravir

Indication: <Enter Response here>

Name of Patient Group: HIV Network of Edmonton Society (HIV Edmonton)

Author of Submission: Catherine Broomfield

1. About Your Patient Group

HIV Edmonton believes health equity and gender equity is a right. We achieve this by honouring community, advocating in partnership to amplify community voices, enhancing responsiveness, and advancing the knowledge that U=U=U: Undetectable equals Untransmittable meaning when a person living with HIV achieves and maintains an undetectable viral load, they cannot transmit HIV sexually; Universal access to testing, treatment, care, and support is central to U=U.

Our vision is to be the foremost organization championing the advancement of health equity, gender equity, and justice in order to eliminate stigma and discrimination. We provide programs, services and engagement activities with and for people living with, or impacted by, HIV and AIDS and other sexually transmitted blood borne infections (STBBI).

Our work to achieve this vision is demonstrated through the development of educational resources made available to community organizations, healthcare professionals and the public; the development and delivery of prevention, health promotion and support programs; and advocacy efforts to give rise to the voice of people living with and affected by HIV and AIDS.

www.hivedmonton.com

2. Information Gathering

HIV Edmonton takes an active stance in listening to our community members – 'peers' (people living with HIV and AIDS, PLWHIV). We provide the following overview of engagements the organization has/has had with PLWHIV in a cross-section of projects and activities that inform our patient input for this submission. All information gathering has taken place in Canada across demographics of respondents living with HIV or at risk of HIV transmission, particularly those from over represented populations in transmission rates: Indigenous Peoples; African, Caribbean, Black (ACB); and gay, bisexual and Men who have sex with men (gbMSM).

During 2022-2023, we were engaged in a peer-led research project to design an implementation under a call for proposals from the Healthy Canadians and Communities Fund of the Public Health Agency of Canada. The call sought proposals on priority populations who face health inequalities and are at greater risk of developing specific chronic diseases: diabetes, cardiovascular disease, cancer and obesity. HIV Edmonton was successful in receiving funding of just under $100,000 for an 18-month project titled: "Chronic Disease and HIV: But I already live with a chronic disease…". The aim of this project was for peers to conduct research and design a wellbeing intervention that would improve quality of life for those living with HIV and reduce the risk of also developing additional chronic diseases. The health promotion design developed by the peer-led research team created a 'peer health neighbourhood' that offers a suite of peer-led connections and supports encircling the PLWHIV. We are enthusiastic about the outcome of the research project and will be submitting for Phase 2 Implementation Funding when the call for proposals is announced in 2024. The research team collected data through 27 interviews with PLWHIV. Of these 18 chose to participate in a series of focus groups that were targeted to specific population demographics: women; African, Caribbean, Black (ACB); Indigenous; gay, bisexual, men who have sex with men (gbMSM); and a general/open focus group. Focus groups were offered in person and virtually; in person was the preferred attendance. Over the course of the project, we conducted a feasibility assessment and rapid prototyping to validate design intervention ideas identified by participants, refined the behaviour change solution based on ongoing participant feedback and considered ways that the design could be qualitatively evaluated which honours lived and living experiences of PLWHA. Feedback collected during this research highlighted the barriers and challenges experienced by peers as they navigated treatment regimes and the impact on their mental health, physical health and experiences of stigma. Injectable medication delivery was anecdotally referenced as a 'wish' that numbers of participants hoped would be available in the future. A vaccine for HIV was another hoped for scientific development that peers identified. As we did not know at the time of this research of the ViiV injectable development we did

not ask specific questions so anecdotal qualitative comments by focus group participants or by the peer researchers is where this 'wish list' item came from.

HIV Edmonton has been part of the Canadian HIV/AIDS Black, African and Caribbean Network(CHABAC) Anti-Black Racism project for several years. We currently host the CHABAC Network in our facility. A central part of the CHABAC project is to capture the Black knowledge system into a 'scorecard' delivery method which facilitates capturing data and input from community in a way that is relatable. Through the course of this project we have had input from ACB peers that exposes the difficulties ACB Canadians have accessing the cascade of care and treatment. Sigma within the ACB community is a significant barrier as the community is small and therefore, association with HIV/AIDS can alienate a person from their support networks or pursuing health decisions. Again, anecdotally, ACB peers have identified injectable delivery for treatment would be a desired option as people currently have only oral medication options that require visiting the specialist and pharmacy frequently. Discretion is a key determinant for a person seeking help and treatment.

3. Disease Experience

Without treatment, HIV progresses to AIDS and the person will die. Therefore, whatever treatment program will facilitate a person accessing testing, treatment, support and adherence to the medication regime with stave off AIDS and death.

Peers consistently and emphatically confirm that HIV stigma drives isolation and mental health challenges that are unlike other chronic health conditions. Peers have identified that any health promotion or health intervention is first and foremost rooted in a shared experience of stigma, discrimination and perhaps racism as a result of a positive HIV health status diagnosis. While intersectionality individualizes the lived experience of a person, Peer Research Team members and focus group participants identified and agreed that stigma, discrimination and racism override other intersections at a fundamental level. First person narratives provide concrete examples of stigma and racism and the impact it can have on a person's ability to access services and feel invested in their wellbeing. If a person feels stigmatized about their diagnosis and the pursuit of treatment, a person will remain in disbelief of their diagnosis and may avoid treatment entirely.

Stereotyping in health care settings based on positive HIV diagnosis AND other intersectionalities such as racialization, substance use, sex work stigmas, homelessness, persist. In HIV Edmonton's experience, avoidance of services has a direct impact on health and wellbeing, if testing, treatment maintenance or medication drop off can be traced to racist or stigmatizing experiences, a person will avoid services and supports.

Adherence to medications requires a degree of stability for a person living with HIV. Medications must be taken with food with specific caloric intake and at regularly timed intervals day in and day out. Oral medications can have damaging impact on the digestive and intestinal systems of the person. This consistency means that a person living with HIV may not be able to engage in 'regular' life events because the timing may coincide with their medication schedule.

Peers report cognitive decline as a result of years of medication adherence.

Please see Disease Experience Testimony letter previously provided for HIV Edmonton's HCCF project which provides insight into the experience of one peer – though is representative of the experience of many.

4. Experiences With Currently Available Treatments

<u>Difficulties</u>

-number and size of pills to be taken daily

-pills must be swallowed and taken with food

-ideally to be taken at the same time daily

-long term use of past and existing medications on bodily systems is harsh; cardiovascular, liver, digestion and cognitive functioning can all be impacted in the long term

-renewal of prescriptions is ongoing

-travel for checkup, prescription refills can be challenging due to the regularity required

-injectable (needle) may not appeal to all

All of these are potential barriers that would be alleviated by access to injectables. If someone is homeless, taking medication with food or at the same time daily is a burden that often cannot be overcome. Renewal of prescriptions can be a barrier as can seeing one's doctor. Long term treatment has been shown to have multiple impacts on bodily systems. Travel to clinics is often a barrier for single parents and those living in poverty.

Benefits

-reduced impact on digestive related issues from consuming pill treatment

-fewer trips for prescription renewal

-living of life is not encumbered by medication regime schedules

-improved mental health as a result of living life more 'normally'

-reduced exposure to health services or systems where stigmatizing experiences occur

-improved self determination as having a choice in treatment decisions as a result of having choice

-for those with life instability injections every few months are more likely to be completed than daily pills because of the ease of a single dose every few months

-likelihood that increased numbers of people living with HIV will seek and maintain their treatment adherence

-increased undectable status as a result of treatment adherence is likely to reduce the transmission rates

These benefits are identified as the most likely by peers who expressed that injectables was a 'wish list' development that would benefit their lives.

5. Improved Outcomes

It may appear shocking to some that peers have expressed that they would trade-off not pursuing existing therapy due to the stigma of accepting an HIV positive diagnosis where their community and support system would know there is something wrong with them if they are taking medication daily. Therefore, people are willing to trade their life for anonymity. Injectables may encourage a greater sense of discretion for someone to adhere to treatment protocols.

If a person is not on regular treatment adherence then they are trading off achieving an undetectable viral load. Furthermore, this means that transmission rates will continue. If undectable viral load could be attained in everyone who is currently HIV positive then there would be no transmissions sexually. While this would not eliminate HIV as there are other vehicles of transmission (blood; chest/breast milk) there would be significantly less transmissions.

The current choice in treatment options by oral pill is limited to that of the drug brand and the body's physiological/biological response to a given drug brand. Approval of the injectable delivery would in fact provide PLWHIV the opportunity to self-determined involvement in treatment decisions as they could choose to have the pill or injectable option.

6. Experience With Drug Under Review

HIV Edmonton acknowledges that we did not collect data from anyone who disclosed their participation in any access to the drug under review through clinical trials, private insurance. Our response is rather a compilation of qualitative statements heard and shared by our peers as they navigate their lives living with HIV.

In summary, key values important to PLWHIV:

-sense of normalcy to not have to take pill medications daily and be 'enslaved' to the taking of medications

-reduced stigma experienced in multiple settings (pharmacy, daily life) as a result of current treatment options

-autonomy and self determination in which treatment option (pill or injectable)

We note that of particular advantage, this injectable anti-retro viral treatment would enable PLWHIV who are precariously housed or houseless in their empowered autonomy with respect to their treatment adherence. Many from this vulnerable population identify that due to the chaotic nature of their living circumstances, keeping their medications safe from the elements or from theft is difficult. Having sufficient food and caloric intake and maintaining the timing rigor of scheduled intake with existing pill form medications is also challenging. Prescription renewal, attending doctors' appointments and other health system interactions are sites of judgement and stigma as the person is houseless and living with HIV. In short, this population's access to injection delivery on a quarterly basis schedule would be advantageous for not only their own adherence and improved health; additionally, the likelihood of attaining undetectable viral load would further contribute to prevention efforts to reduce HIV transmission.

7. Companion Diagnostic Test

HIV Edmonton is not aware of companion diagnostic testing applicable in this instance.

8. Anything Else?

Our Healthy Communities and Canadians Fund research empowered peers to 'dream' together about what health equity could feel like and endowed community to share what health means to them. The project allowed the conversation to move from 'what is harmful in healthcare' towards 'what can we do to help people living with HIV and AIDS to feel safe in healthcare'. For those that were involved in the Project, there was increased understanding of the healthcare experience that PLWHA deserve, which is reflected in the ultimate intervention design - healthcare that is safe, welcoming, and provides space for people to articulate their specific health needs AND is driven by their autonomy and creating interdependent capacity in an individual's health ecosystem. HIV Edmonton is grateful for the opportunity to submit this feedback for review and thanks for review committee for its tireless work to ensure the access to medications that support the health and quality of life for those living with HIV. In approving this drug for access to PLWHIV you will be adding to the autonomy of PLWHIV to self-determine how they live with their disease.

Appendix: Patient Group Conflict of Interest Declaration

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

Notification of the call for patient group submission being open was received from ViiV Healthcare, [redacted].

Assistance received from the Health Coalition of Alberta, [redacted] to understand the CADTH patient group submission process including what type of lived experience information versus academic research might be valuable to the review process.

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.

Yes, through the data gathering and analysis in our HCCF peer-led research project, we hired a third party contractor as a Health Design Consultant. This consultant was [redacted] M.Des of Design for Health (www.designerly.ca).

No other outside help is attributable to the data used in submission.

List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Health Canada				X
Public Health Agency of Canada				X
Alberta Health				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: Catherine Broomfield

Position: Executive Director

Patient Group: HIV Network of Edmonton Society (HIV Edmonton)

Date: February 7, 2024

A letter from a senior and long-term HIV survivor

December 16, 2021

Healthy Canadians and Communities Fund Public Health Agency of Canada

Letter of Support for:

Chronic Diseases & HIV: But I Already Live With A Chronic Disease

HIV Edmonton

9702 111 Ave NW

Edmonton, AB T5G 0B2

I am providing this Letter of Support for the above named application for a program funding application submitted by HIV Edmonton.

As a member of Edmonton's gbMSM community since 1969 and actively involved over the many decades in a number of 2SLGBTQIA+ community organizations and businesses, I have been witness to the devastation that HIV/AIDS caused and still causes in the Greater Edmonton Region.

In fact, I was diagnosed with Stage 3 (AIDS) HIV infection in April of 1998. My own journey with this disease was one of despair brought on by the medications and minimal life expectancy prognosis, noncompliance with medications, re-igniting my will to fight then succumbing to the effects of the disease and the medications forcing me out of the workforce, the collapsing of my body's gastrointestinal and endocrine systems, rallying against the arrogance of medical professionals stuck in out-dated thinking and after finally being heard, moving forward on a path leading to a health recovery that was never in my wildest dreams imagined.

As a senior and long-term HIV survivor there are few resources available that address the effects of being on the early HIV medications and the damage they do to the body as well as dealing with an aging body complicated by an early infection many years ago that can lead to greater opportunity for opportunistic infections, cancer, dementia and more. Many of the existing HIV agencies

have developed great resources for those newly diagnosed but are lacking in programs aimed at those who have lived with the disease for many years.

The biggest challenge I have faced was dealing with health professionals who remained stuck in older treatment plans and were unwilling to hear of other options, researched by their patients themselves, from today's vast resources now available on the web. This is where a program which seeks to generate input and ideas from those who have lived with HIV and the experiences they have had in their own journeys leading to where they are today in their health... physically, mentally and emotionally... is very much needed.

Having to "fight my way back to health" I do have wisdom derived from my experiences that should be shared so others may benefit. And I know many others within our gbMSM community that also have unique experiences and their own wisdom that can be put together into a program that can effectively provide support for those of us living with this chronic disease.

HIV Edmonton has been a leader in our community since its inception as the AIDS Network of Edmonton in 1984. I have been proud of contributing to their success in many ways – from helping raise the first $805.00 in early 1984 that eventually lead to the opening of the AIDS Network of Edmonton's first office, assisting in a myriad of fund raisers to supplement their funding over the years that followed, acting as a co-sponsor with them and the Northern Alberta Infectious Disease Clinic in applying for fast-tracked approval from Alberta Health for the very first rapid HIV test, serving on a committee to explore ways to re-engage the gbMSM community to recent engagements as they look to the future after the pandemic.

I am confident that HIV Edmonton will succeed in this new program due to their diligence and sustainability in Edmonton as a health information and support resource. Their commitment to engaging others in the community to help lead this program will ensure that it becomes one where peer support and information will be at the forefront. I am pleased to support their application for funding and hope that your approval will open opportunities for myself and others in our community to share the wealth of information available... yet untapped.

Regards,

Name of Drug: cabotegravir
Indication: HIV-1 infection, pre-exposure prophylaxis
Name of Patient Group: CATIE
Author of Submission: Jody Jollimore, Christie Johnston, Sean Hosein

1. About Your Patient Group

CATIE is Canada's HIV, hepatitis C, and STBBI knowledge exchange broker and a trusted national source for up-to-date, unbiased information about HIV, hepatitis C, and related STBBIs. Through resource development and dissemination, community capacitybuilding and skills-building, and convening, CATIE connects people living with HIV or hepatitis C, at-risk communities, healthcare providers, and community organizations with the knowledge, resources and expertise to reduce HIV, HCV, and STI transmission and improve quality of life.

Originally founded in 1990 to share information among people living with HIV about new and emerging treatments, CATIE's mandate has expanded to providing both treatment and prevention information on HIV and hepatitis C to frontline service providers across Canada. Our full legal name is the Canadian AIDS Treatment Information Exchange, but today we operate under the name CATIE.

CATIE Website

2. Information Gathering

This input template includes a summary of information gathered through multiple activities. Through CATIE's education evaluation activities, we assess knowledge and resource strengths and gaps, including in the area of HIV PrEP. These evaluations occur with each HIV prevention education activity (~15 per fiscal year) and have occurred for the past 10 years. CATIE also engages in ongoing consultation with community-based organizations, people affected by HIV and patient groups through partnership and collaboration. CATIE is a participant on multiple projects and research projects that focus on HIV prevention; through this, we are able to gather input on HIV prevention needs and gaps in diverse communities of people at risk of HIV including Indigenous people, gay, bisexual and other men who have sex with men, African Caribbean and Black communities, and people who use drugs. Finally, we play a leadership role in the synthesis of HIV prevention knowledge for frontline service providers and communities at risk. Through this process, we gather input from international published literature.

3. Disease Experience

Given advances in HIV treatment, HIV can be considered a chronic, manageable illness. The use of HIV treatment not only improves the health of people living with HIV but also is a highly effective strategy to prevent HIV transmission. To achieve and maintain an undetectable viral load, people living with HIV need to take their HIV treatment as prescribed for the rest of their lives. In addition, regular medical visits are important to monitor viral load to make sure it stays undetectable and to receive other medical support. The experience of adherence to medication for HIV varies from person to person; for some individuals, it can be challenging.

Without HIV treatment, the immune system of a person living with HIV can become too weak to fight off serious illnesses, and they can eventually become sick with life-threatening infections and cancers. HIV infection is associated with excess inflammation that is only partially reduced with effective HIV treatment. Some researchers think that excess inflammation associated with HIV infection may, over many years, contribute to accentuated aging in this population. We do know that people living with HIV can be at increased risk for co-infections and cancers, and managing HIV can become more complex as people age.

Despite advances in HIV treatment, HIV stigma and discrimination persist in Canada. HIV sigma can have a significant impact on the health and well-being of people living with or at risk of HIV. HIV stigma exists at the system level in our laws and institutions, through communities, and, between individuals or by oneself in the form of shame and guilt. HIV-related discrimination can cause job loss, violence or criminalization. It can also encourage people living with HIV to delay enrolment in care, impacting longer-term health

outcomes. Stigma associated with living with or being at risk of HIV poses a barrier to HIV prevention, care and treatment and negatively affects the quality of life of those affected by HIV.

4. Experiences With Currently Available Treatments

According to the Government of Canada, in 2020, an estimated 1,520 new HIV infections occurred in Canada, a slight decrease from the similar estimate in 2018. New HIV infections were recorded in all of Canada's priority populations where data exists; the proportion of new infections among gay bisexual and other men who have sex with men (gbMSM) continued to decrease (but new infections did occur); the proportion of new infections among people who inject drugs, Indigenous peoples and women slightly increased.

There is consensus that no single HIV prevention strategy will be sufficient to control the HIV pandemic. While effective biomedical HIV prevention options exist, such as oral daily HIV pre-exposure prophylaxis (PrEP) and the use of HIV treatment in people living with HIV to prevent transmission, these tools must be accessible, desirable, and taken consistently and correctly to have an impact. Not all people affected by HIV are able to access or use these tools consistently for a variety of reasons; barriers such as HIV stigma, limited access to health care services, and challenges with daily adherence to prevention strategies limit the uptake of existing tools among some people at risk for HIV. Oral PrEP uptake remains low in Canada, even among at-risk gbMSM. Despite the efficacy of oral PrEP, there is an increasing realization that multiple prevention options are needed to meet the varied needs of populations.

Even among gbMSM where we've seen the greatest uptake of PrEP, those most at-risk are less likely to access PrEP due to certain upstream factors impacting their ability to engage with the healthcare system (anti-Indigenous racism, anti-black racism, homophobia, etc.)

5. Improved Outcomes

Access to injectable forms of PrEP could help to increase the number of people taking PrEP by providing more options for people from which to choose. A good example of how more choice can lead to higher uptake is from the research on contraception. The first form of hormonal contraception was an oral pill but over time a variety of longer-acting options became available, such as an injection, a patch, intrauterine devices (IUDs) and more. Research shows that as the number of options for contraception increased so did the overall uptake, as people had the ability to choose an option that would work for them. A study among gbMSM in Toronto supports this idea. In the study, participants were asked about their willingness to take various forms of PrEP. As more potential options were included, the proportion of people who indicated interest in taking *any* form of PrEP increased.

Studies have found some potential advantages of injectable PrEP compared with oral PrEP, which may help to address certain barriers to oral PrEP identified by populations at risk for HIV, such as adherence and stigma. A major advantage of injectable PrEP is that for some people daily pill taking is a barrier to PrEP and injectable PrEP overcomes some of these barriers. This was reported in studies of various populations, although different populations face different challenges associated with daily pill taking. For example, some people who use drugs report that remembering to take oral PrEP can be a challenge while they are using drugs or dealing with competing priorities. Concerns about safely storing PrEP medications for those who are homeless or on the street can also be a barrier to taking daily pills. For some people, the fact that injectable PrEP is more discreet than oral PrEP is seen as an advantage. For example, Black women and young gbMSM have reported a preference for injectable PrEP because it can help to avoid PrEPrelated stigma. As another example, the discretion of injectable PrEP can be a benefit for people experiencing intimate partner violence who worry about a controlling partner finding their pills.

A greater array of PrEP options could help to further increase PrEP uptake among populations at risk for HIV in Canada. For some people unable to access other forms of HIV prevention consistently, injectable long-acting PrEP in the form of long-acting cabotegravir could meet their HIV prevention needs.

6. Experience With Drug Under Review

We know of a handful of patients we know had access to the drug (injectable PrEP) from providers in another country (U.S). These patients were men who have sex with men. The advantages were that the drug only needed to be injected ultimately every two months. This was very helpful for the patients as it relieved them from having to remember to take a pill every day. The injections caused a moderate degree of pain as they were injected deep into the buttocks. However, the pain resolved within hours to one day. Apart from temporary pain and injection site reactions, there were no side effects. The drug was better tolerated than oral PrEP which

was associated with diarrhea, nausea and headache. Another benefit to the patients who used injectable PrEP was that they did not have to store the drug in their home. Even though the patients are HIV negative, tenofovir-containing medicines (Truvada and Descovy) are associated with HIV treatment and so there can be stigma generated towards the patient by potential partners if tenofovir was found in their home. There may be subgroups for whom injectable PrEP is best suited – people who have adherence issues; people who have difficulty taking pills; people who are intolerant to tenofovir-containing medicines. The sequencing of drugs that participants used prior to injectable PrEP were as follows: oral TDF + FTC (generic Truvada); then oral Descovy (Tenofovir alafenamide + FTC); then ultimately injectable PrEP

Companion Diagnostic Test

Not applicable.

8. Anything Else?

Oral PrEP has had a large impact by decreasing the spread of HIV in high-income countries where it has been studied for this purpose in demonstration projects – in England and Australia. In clinical trials, injectable PrEP is highly effective, about 67% more effective than oral TDF + FTC. This increased effectiveness is chiefly due to reduced adherence requirements for injectable PrEP. This is a tremendous advantage for people who use injectable PrEP. Although oral PrEP is very useful, some, perhaps many people will develop adherence issues over the medium- and long-term. Injectable PrEP has the potential to help keep more people HIVnegative and for longer than with oral PrEP. Young MSM are particularly at risk for HIV and younger people tend to have more adherence issues than older people. Injectable PrEP has the potential to help keep them HIV-free and many others too. People who take PrEP are generally do not have a history of medicalization; that is, they are not used to taking medicines over the long-term whether intermittently or on a daily basis. Although intermittent PrEP (so-called “on demand PrEP”) may be an option for some people, it requires foresight and the ability to accurately forecast sexual encounters. Therefore on-demand PrEP is not a solution for adherence issues that people have with daily PrEP. Injectable PrEP with its infrequent dosing may be very useful for patients interested in preventing HIV. It may also revolutionize public health approaches to HIV prevention and reduce the burden of monitoring adherence.

Appendix: Patient Group Conflict of Interest Declaration

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

No.

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.

Yes. Multiple Canadian and international published studies were reviewed and synthesized to support the development of knowledge-building products available on the CATIE website. Those products were used in the development of this submission.

List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000

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: Christie Johnston

Position: Director, Education and HIV/STI Knowledge Mobilization

Patient Group: CATIE

Date: February 12, 2024

Name of Drug: Cagotegravir

Indication: HIV-1 infection, pre-exposure prophylaxis

Name of Patient Group: Community-Based Research Centre

Author of Submission: Chris Draenos

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

https://www.cbrc.net/

Community-Based Research Centre (CBRC) promotes the health of people of diverse sexualities and genders through research and intervention development.

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.

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 non-profit that provides leadership to 2SLGBTQ+ community organizations and conduct community-led research with PI Dr. Nathan Lachowsky with research ethics provided through the University of Victoria. Research collected is from Sex Now, which is CBRC's principal community-based research initiative and Canada's largest and longest running survey of gay, bisexual, queer men (cis and trans), non-binary and Two-Spirit people's health. Originating at Pride festivals across British Columbia in 2002, Sex Now has been administered both online and in-person at events across Canada in both official languages. Often referred to as "the gay census", Sex Now has become an essential source of data on the health and well-being of GBT2Q in Canada, and is widely used by community, public health, research, and policy stakeholders.

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 this is a focus on prevention, HIV is one of the most stigmatized diseases, impacting the most marginalized. In regards to HIV prevention, more options are desperately needed. Previous prevention options included pills taken daily or on-demand. There are many barriers to taking a daily pill, and many people who are good candidates for HIV PrEP find daily medication a barrier.

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).

From our recent surveys amongst gay, bisexual, queer men (cis and trans), non-binary and Two-Spirit people, there is evidence that there are barriers, challenges and dissatisfaction with current medication options which has led to sub-optimal uptake of HIV PrEP.

In our Sex Now 2021 survey conducted online, amongst all 2S/GBTQ+ men 90% were aware of HIV PrEP as a medication to prevent HIV. There were significant disparities in knowledge about access for Indigenous people, as only 50% were aware that the medication is covered by the Non-Insured Health Benefit Program. Only 17% of HIV negative 2S/GBTQ+ men were using HIV PrEP and only an additional 9% had ever used HIV PrEP before. However, 92% of believed that sexually active people in the 2S/GBTQ+ community should use PrEP. More than 80% of participants had at least one indication for HIV PrEP based off of the current HIV PrEP guidelines. More than one-third of 2S/GBTQ+ not on HIV PrEP were interested in accessing the medication, with another one-third unsure if they would like the medication. Reported barriers include: concern about side effect from the existing medication option (25%), unable to afford the cost out of pocket (23%), not wanting to take a daily medication (20%), not having enough information (20%), inability to access a care provider to prescribe the medication (15%), low perceived risk of acquiring HIV (14%), worried about judgement from the healthcare provider (12%), concerned about frequency of clinic visits (11%), and judgement from the community (7%). The option for injectable cabotegravir that is covered by public funded programs (ideally universal coverage) would address the top three barriers/concerns that 2S/GBTQ+ have related to taking HIV PrEP.

As a point of comparison, in our Sex Now 2022 survey conducted through venue-based recruitment at Pride Festivals and other queer spaces, amongst people living with HIV (n=144), only 19% preferred taking daily oral pills versus an injectable medication taken every 2 months, with 47% preferring the injectable. This shows a strong desire for innovation in the HIV sector is needed to reduce the burden of taking medication on our community (e.g. long-acting agents).

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?

This medication is administered in bimonthly intervals, for people who experience adherence issues with daily oral medications, this is a game changer. Aside from oral medications taken daily or on demand, there are no other medical prevention options. The consequence of not prevention HIV is continued HIV acquisition at high rates in the 2S/GBTQ+ community, with some people progressing to AIDS, which includes disability and premature death. For our community there is an increased likelihood of those people passing on HIV if they are sexually active or sharing injection supplies with others. It would be highly unethical for this to not be available. We cannot state with stronger words, the importance and urgency to approve this medication.

Generally folks in this situation are also facing barriers in the social determinants of health. Outside of the medical model, considerations need to be made for how pharmaceutical companies are finding ways to support medication adherence (e.g. social supports, income supports, food security, housing security, mental health support).

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? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

People living with HIV have been using the medication (plus 1 additional injectable medication) in the past few years.

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.

N/A

8. Anything Else?

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

N/A

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, 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.

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

ViiV Healthcare ULC provided CBRC with a PowerPoint presentation outlining information about Cagotegravir detailing unmet need, clinical indication, efficacy/safety and explaining the CADTH process.

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

List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

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Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Gilead Sciences Canada, Inc.				X
ViiV Healthcare ULC				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: Chris Draenos

Position: Nurse Practitioner

Patient Group: Community-Based Research Centre

Date: Feb 11, 2024

Name of Drug: Cabotegravir

Indication: HIV infection, pre-exposure prophylaxis

Name of Patient Group: Peer Outreach Support Services & Education (POSSE)

Author of Submission: Kimm Kent, Director

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

POSSE is a youth-driven, harm reduction and human rights training and peer outreach project, for youth between the ages of 15-35. POSSE educates youth to become peer outreach workers within their community. Trained youth then assist and educate their peers, reaching youth where they're at, during street-level outreach, regarding violence, homelessness, harm reduction, substance use, sexual health, exploitation, human trafficking, human rights, and sexualized violence.
https://www.posseproject.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.

Peer Outreach Support Services & Education (POSSE), Director has over 30 years experience supporting 2 Spirit, lesbian, gay, bisexual, trans, queer (2SLGBTQIA=) folx, people using substances and people engaged in sex work or sexually exploited folx, including Indigenous people living on and off reserve, who have been affected by HIV. Input has been provided by staff from POSSE as well as service users.

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?

Not everyone is impacted by the virus the same, this is largely due to socio-economic differences and experiences of marginalization. People who are vulnerable as a result of homelessness, poverty, rural isolation, immigration, Indigenous status and are still facing stigma and barriers accessing or remaining in treatment. Stigma within the medical profession and communities at large continues to be a huge barrier for people seeking medical care, accessing treatment, supports and other services, often preventing people from seeking treatment / supports. People living with HIV, especially those with various intersections of marginalization, impacting every aspect of the quality of their lives and sense of self worth.Youth also struggle with adherence to medications requiring solutions reducing adherence requirements.

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).

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, improved access to medication, a good check point for patient to connect with a health care provider, reduces missed medication (pills), decreasing breakthrough infection, increasing risk of resistance.

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? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

N/A

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.

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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.

N/A

8. Anything Else?

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

Having more medication options available for people living with HIV, and an option that does not require daily medication doses, is ideal for marginalized populations we support.

Appendix: Patient Group Conflict of Interest Declaration

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

No

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

List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$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: <Kimm Kent

Position: Director

Patient Group: Peer Outreach Support Services & Education (POSSE)

Date: January 15, 2024

Clinician Group Input

CADTH Project Number: SR0825-000

Generic Drug Name (Brand Name): Cabotegravir

Indication: Prevention HIV infection

Name of Clinician Group: Vancouver Coastal Health Regional HIV Program

Author of Submission: Dr Sarah Stone

1. About Your Clinician Group

We are completing this on behalf of the Vancouver Coastal Health (VCH) Regional HIV Program, a Public Health program that aims to reduce the rate of HIV infection among the 1.25 million people living in the region. Collectively with Public Health Nurses, we monitor and evaluate every new HIV diagnosis in the region, and undertake contact tracing and follow-up. We also fund clinical services focusing on HIV prevention and care. Our program has been an integral component of the implementation of Pre-Exposure Prophylaxis (PrEP) since 2018. The clinics associated with the VCH HIV program prescribe the vast majority of HIV PrEP in VCH. 2.

2. Information Gathering

The Information gathered in this submission is from data available on the BC Centre for Excellence in HIV annual report in conjunction with individual chart reviews of every new HIV diagnosis in our region.

3. Current Treatments and Treatment Goals

After a robust investment in HIV testing, treatment, care and prevention (part of the Provincial From Hope to Health Initiative: https://www.health.gov.bc.ca/library/publications/year/2012/from-hope-to-health-aids-free.pdf), we are fortunate to have seen a significant decline in new HIV infections in British Columbia (BC). Since the introduction of oral HIV PrEP, new infections declined from 182 new cases in BC in 2017 to approximately 80 in BC in 2022. PrEP has been an important component of HIV prevention for individuals who have the ability to adhere to a daily regimen of oral medication.

4. Treatment Gaps (unmet needs)

However, we continue to see new infections in a group of higher-risk individuals, most of whom are vulnerable people who have difficulties adhering to oral therapies due to complex psychosocial and intersecting circumstances (e.g. psychoactive substance use, mental illness, poverty, homelessness etc.). In 2022, over 20% of new HIV infections identified in VCH were in individuals who had previously been on oral PrEP but were unable to adhere to therapy. This highlights that we are able to identify those at higher risk for HIV, but they are not being served by our current pre-exposure prophylaxis optionGiven this data, and the ongoing high rates of HIV transmission in provinces such as Saskatchewan and Manitoba, there is still much work to be done if we hope to reach our shared goal of ending the HIV epidemic in Canada by 2030.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

We believe the use of an injectable long-acting option for PrEP is the most appropriate tool in preventing new infections in this very vulnerable, higher-risk patient population. We have the infrastructure in place to enable the delivery of an evidence based injectable therapy that is a more feasible approach to prevention for such a high-risk group. Long-acting injectable Prep would also be appropriate for those individuals who would face stigma or discrimination if their use of oral HIV Prep were to be disclosed. And lastly individuals who are unable to tolerate daily oral Prep medications due to side effects or have difficulties managing the consistent requirement for daily oral ingestion of HIV Prep medications.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Patients that would be best suited to long-acting injectable HIV Prep would be those individuals in whom adherence to oral daily HIV Prep is difficult. These difficulties could be for a variety of reasons including challenges with adherence, swallowing difficulties and side effects with oral medications.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

In clinical practice we look at how many individuals become HIV positive quarterly in our region. We also examine the factors that contribute to these infections. One of the trends we see with people who are infected with HIV who were previously offered or on oral HIV Prep, is an inability to continue with oral therapy due to a variety of psychosocial issues including mental illness and substance use. A meaningful response to treatment would demonstrate a further reduction in new HIV infections in our region - and in particular in the subgroup of individuals who have had difficulty remaining on oral HIV Prep

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

We are aware that the long acting injectable Cabotegravir can remain at detectable levels in the serum for months after cessation of injectable therapy. Therefore a robust monitoring and follow up strategy must be in place in order to prevent any new HIV infections in folks that have discontinued injectable HIV Prep and also to prevent the development of any drug resistance in the HIV virus exposed to sub-therapeutic drug levels.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

This drug would be used appropriately both in community, hospital and specialty clinics. We would suggest that a clinician with expertise in managing HIV be involved in the prescribing and monitoring of long acting Coabotegravir for HIV Prep. In many cases this will be an Infectious Disease specialist but this could also include family practitioners and nurse practitioners with a specific interest and expertise in treating HIV.

6. Additional Information

We have reviewed the data on long acting Cabotegravir for HIV prevention and would request that CADTH consider reimbursement for Long Acting Cabotegravir for HIV-PrEP as soon as possible.

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

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

NO

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

NO

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. Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.

Declaration for Clinician 1

Name: Dr Sarah Stone

Position: Medical Director of HIV for Vancouver Coastal Health

Date: 21/01/2024

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

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name		GSK/Viive		
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Althea Hayden

Position: Medical Health Officer, Vancouver Coastal Health

Date: 07-02-2024

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

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to**	**$5,001 to**	**$10,001 to $50,000**	**In excess of $50,000**

	$5,000	$10,000		
Add company name	N/a	N/a	N/a	N/a
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Patricia Daly

Position: Chief Medical Health Office Vancouver Coastal Health

Date: <09-02-2024 >

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

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name	N/a	N/a	N/a	N/a
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name:Mark Hull

Position: Infectious Disease Physician and HIV Prep expert

Date: < 09-02-2024 >

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

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name	N/a	N/a	N/a	N/a
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name:William Connors

Position: <Infectious Disease Physician and HIV Prep Expert

Date: 02-09-2024

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

Table 5: Conflict of Interest Declaration for Clinician 5

Company	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name	N/a	N/a	N/a	N/a
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Misty Bath

Position: Director of Clinical Programs – Substance Use & Priority Populations (Vancouver Coastal Health Authority, Office of the Chief Medical Health Officer).

Date: <05-02-2024>

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

Table 1: Conflict of Interest Declaration for Clinician 1

Company	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name	n/a	n/a	n/a	n/a
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

CADTH Project Number: SR0825-000

Generic Drug Name (Brand Name): Cabotegravir

Indication: Pre-exposure Prophylaxis for HIV infection

Name of Clinician Group: N/A

Author of Submission: Philippe El-Helou (myself)

1. About Your Clinician Group

Personal submission (not a group)

2. Information Gathering

I have completed medical school at the University of Ottawa in 1992, my internal medicine residency at the University of Toronto in 1996, and my infectious diseases fellowship at Beth Israel Medical Center in New York in 1998. I have been practicing in the field of infectious diseases, including HIV medicine, since 1998.

Since 2006, I have been an Associate Professor in the Division of Infectious Diseases in the Faculty of Health Sciences at McMaster University. Between 2001 and 2006 I was an Assistant Professor. Between 2003 and 2018, I was the clinical medical director of the HIV Clinic at McMaster University Medical Center in Hamilton. I was a member of the board of directors of the Ontario HIV Treatment Network (OHTN: a backbone organization that supports HIV research and clinical care in Ontario) between 2014 and 2020 and I have currently rejoined the Board of Directors of OHTN in Sept 2023.. Since 2015, I have been the physician lead for the Ontario HIV Clinic Network (a network of all medical clinics treating persons living with HIV in Ontario).

Since 2018, I have been providing Prep (Pre-exposure Prophylaxis for HIV infection for more than 600 patients at the Maple Leaf Prep Clinic in downtown Toronto.

3. Current Treatments and Treatment Goals

In Ontario, Canada, Pre-Exposure Prophylaxis (PrEP) is available as an HIV prevention option. Here's some specific information about PrEP in Ontario:

1. **Access to PrEP:** PrEP is available in Ontario with a prescription from a healthcare provider. It's typically prescribed to individuals who are at higher risk of acquiring HIV, such as those who are in serodiscordant relationships (where one partner is HIV-positive and the other is HIV-negative), men who have sex with men (MSM), people who inject drugs, and other individuals at increased risk.

2. **Coverage and Cost:** In Ontario, only generic Emtricitabine/Tenofovir disoproxil fumarate is covered by the Ontario Drug Benefit (ODB) program for eligible individuals. This means that for those who qualify, the cost of PrEP medications may be covered under provincial drug coverage plans, such as the Ontario Drug Benefit or the Trillium Drug Program. However, coverage criteria and copayment requirements may vary.

3. **PrEP Medications:** The PrEP medications approved for use in Ontario are Truvada (emtricitabine/tenofovir disoproxil fumarate) and Descovy (emtricitabine/tenofovir alafenamide). These medications are taken once daily to reduce the risk of HIV transmission. There are generic formulations of Truvada that are cheaper. There are no generic formulations of Descovy available in Canada so far.

4. **Access Points:** PrEP can be prescribed and monitored by various healthcare providers, including family doctors, nurse practitioners, and specialists in HIV care. Sexual health clinics, community health centers, on-line clinics and specialized HIV clinics are also resources where individuals can access PrEP prescriptions, HIV testing, and ongoing care.

5. **Education and Support:** Ontario has resources available to educate individuals about PrEP, including information on its effectiveness, how to access it, and potential side effects. Support services are also available for those who are prescribed PrEP, including adherence counseling and monitoring for side effects.

6. **Public Health Initiatives:** The Ontario Ministry of Health, in collaboration with local public health units, implements initiatives aimed at increasing awareness of HIV prevention methods, including PrEP. These initiatives may include public education campaigns, training for healthcare providers, and efforts to reduce stigma associated with HIV and PrEP use.

The Goal of Prep is to decrease the incidence of newly acquired HIV infections.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

The current available options of PrEP medications approved for use in Ontario are Truvada (emtricitabine/tenofovir disoproxil fumarate) and Descovy (emtricitabine/tenofovir alafenamide). These medications are taken once daily to reduce the risk of HIV transmission. There are generic formulations of Truvada that are cheaper. There are no generic formulations of Descovy available in Canada so far.

The cost of Descovy is around 1000 per months and is only an option for patients with private drug plans.

The current medications are oral tablets that require excellent compliance on behalf of patients

5. Place in Therapy

Cabotegravir LA is an antiretroviral drug that has shown promise in HIV prevention as part of pre-exposure prophylaxis (PrEP). PrEP is a preventive strategy where people who are at high risk of HIV infection take medication to reduce their risk of contracting the virus. The role of injectable cabotegravir(brand name: CAB LA) in PrEP is significant for several reasons:

1. **Long-acting formulation**: Cabotegravir for PrEP is administered as a long-acting injectable (LA), typically given once every two months. This is in contrast to daily oral PrEP medications like Truvada (tenofovir disoproxil fumarate/emtricitabine) or Descovy (tenofovir alafenamide/emtricitabine). The long-acting formulation can potentially improve adherence, as individuals do not need to remember to take a pill every day.

2. **Efficacy**: Clinical trials have demonstrated that cabotegravir is highly effective in preventing HIV transmission. For example, the HPTN 083 and HPTN 084 trials showed that cabotegravir was superior to daily oral PrEP in preventing HIV acquisition among cisgender men and transgender women who have sex with men and among cisgender women.

3. **Choice for individuals**: Some individuals may prefer long-acting injectable PrEP over daily oral medication due to lifestyle factors, concerns about adherence, or stigma associated with taking a daily pill associated with HIV prevention.

4. **Addressing adherence challenges**: Adherence to daily oral PrEP has been a challenge for some individuals, leading to suboptimal effectiveness. Long-acting injectable PrEP offers an alternative that may help address adherence issues and improve overall effectiveness.

5. **Expanding prevention options**: Having multiple options for HIV prevention allows healthcare providers and individuals to choose the method that best fits their needs and preferences. Cabotegravir adds to the toolkit of available prevention strategies, potentially increasing the reach and impact of HIV prevention efforts.

Overall, the role of cabotegravir in PrEP represents a significant advancement in HIV prevention, offering an effective and potentially more convenient option for individuals at high risk of HIV infection. However, it's essential to consider individual preferences, cost, accessibility, and other factors when determining the most suitable HIV prevention strategy for each person.

5.1. How would the drug under review fit into the current treatment paradigm?

The current options are oral tablets only.

IM Cabotegravir will add widely to the therapeutic landscape of HIV prevention.

It is considered another first line option

It will shift the current treatment paradigm as it will be the only IM options every two months.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

As I mentioned earlier, currently the only treatment options for Prep are oral tablets.

IM Cabotegravir is a game changer as it allows a twice monthly injection (6 IM injections per year)

IM Cabotegravir has been also studies in multiple populations (men, women , transgender females)

IM Cabotegravir is an alternative option for those who can be compliant with daily tablets.

Diagnostic testing for HIV is performed by standard methods (HIV serology/ HIV RNA PCR)

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Prep trail outcomes are defined by number of study patients that seroconvert and get infected with HIV.

The outcomes in clinical practice are the same. (Incident HIV infections)

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

IM Cabotegravir has a long tail end of medication. Once the IM Cabotegravir is disconitued, the patient will need to be treated with oral meds if they are at risk of acquiring HIV infection

5.5What settings are appropriate for treatment with Cabotegravir? Is a specialist required to diagnose, treat, and monitor patients who might receive Cabotegravir?

Access Points: PrEP can be prescribed and monitored by various healthcare providers, including family doctors, nurse practitioners, and specialists in HIV care. Sexual health clinics, community health centers, on-line clinics and specialized HIV clinics are also resources where individuals can access PrEP prescriptions, HIV testing, and ongoing care.

Cabotegravir should be prescribed by providers prescribing Prep currently

6. Additional Information

None

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

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

None

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

   None

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. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Philippe El-Helou

Position: Associate Professor Medicine McMaster University

Date: 12/02/2024

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

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Viiv		X		