

## Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Truvada (emtricitabine / tenofovir disoproxil fumarate) for Pre-Exposure Prophylaxis of HIV-1 Infection	
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Permission is granted to post this submission	Yes	

### 1.1 & 1.2 Submitting Organization & Conflict of Interest

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 meaningfully engages community members, service providers, policymakers and other stakeholders to identify, develop, and implement policy and program solutions. In fiscal 2015/16, CTAC received unrestricted organizational and educational grants from Gilead Sciences, AbbVie, and ViiV Healthcare.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

CTAC held two public national consultation webinars (14 and 15 March 2016) for Truvada for HIV pre-exposure prophylaxis (PrEP) attended by a total of 21 people. In each webinar we reviewed the regulatory pathway, from clinical trials through public formulary listings. We presented clinical trials data and clinical indications as per the Product Monograph, and responded to questions. The webinars were advertised through CTAC's website, social media, and CTAC member/partner communications. Webinar attendees were invited to complete an on-line, anonymous survey. A recording of the webinar, and a link to the on-line survey, were posted on CTAC's website and promoted on social media. **Twenty surveys were completed and analyzed for this submission. Quotes contained in this submission are reproduced exactly from those surveys.** (Note that not all questions were mandatory, and some answers were not mutually exclusive so values may not add up to 20 or 100%.) Respondents' age range was 25 to 58 years, median 33 years. Fifteen of 18 respondents reported male gender, with two female and one transgender man. Seventeen of 18 reported gay, bisexual or queer sexual orientation. Respondents reported obtaining prescription medications out of their own money (28%), through private insurance (56%), public drug programs (39%), or clinical trial participation (6%), and one person reported importing. **Nine of 20 respondents (45%) reported current or past use of Truvada for HIV PrEP.** Seven (78%) of those people reported current PrEP use for median of 12 months (range 3 to 36 months); 2 reported past use for 12 months.

### 2.2 Impact of Condition on Patients

In Canada, HIV infection is significant from individual clinical and population health perspectives. Adults at substantial risk of HIV infection have sought Truvada "off-label" and through clinical trials to reduce their risk of acquiring HIV infection. The human immunodeficiency virus (HIV) is a retrovirus that left

untreated progressively destroys a person's immune system, resulting in excessive morbidity and premature death. Among heterosexuals, it has been estimated that the consistent use of condoms results in 85% reduction in HIV incidence arising from heterosexual intercourse, a reduction similar to, although lower than, that for contraception. (Weller 2009; CD003255) Recently it has been estimated in a study of men who have sex with men (MSM), condom effectiveness was 70% among those who use condoms consistently—yet only 16% of MSM reported consistent condom use. (Smith 2015; PMID: 25469526) Recent Canadian data summarized by the Public Health Agency of Canada shows that despite the fact that condom-less anal intercourse is the most common risk factor for HIV acquisition, a significant subset of MSM engage in condom-less anal sex. Factors associated with condom-less anal intercourse included unavailability and difficulty using condoms, trust and relationship issues, momentary lapses, depression and stress, and assumptions about partners and situations. (PHAC 2013; ISBN: 978-1-100-21880-9)

Over the past decade in Canada, HIV incidence peaked in 2008 and has only gradually declined since that time, despite available methods of preventing HIV transmission. In 2014, 2044 new HIV cases were reported to PHAC. Where exposure pathway was reported, approximately 49% of cases were attributable to sex among MSM, 29% to heterosexual sex, and 13% to injecting drug use. (PHAC 2015; ISSN 1701-4158) Estimates of HIV incidence and prevalence eclipse these case reports. PHAC estimates that 75,500 (range 63,400 to 87,600) people were living with HIV and that 16,020 (range 13,000 to 19,000) people with HIV were undiagnosed at the end of 2014, representing 21% of all cases. (PHAC 2015; ISBN: 978-0-660-03780-6) A recent analysis of the ongoing HIV epidemic among BC gay men highlights the need for multi-pronged strategies to prevent HIV: “The challenge with current approaches to sexual health and related HIV prevention strategies is that they are simplistic and reductionist, assuming that decisions about sex are made based solely on knowledge about HIV transmission and weighing of potential risks; thus, they fail to recognize the intrinsically human feelings and desires that propel human sexuality.” (BCMOH 2014; [HIV, Stigma and Society](#)) The complex interplay of behaviours and socially structured life experiences also challenge existing HIV prevention efforts among other populations disproportionately affected by HIV in Canada (i.e., Aboriginal people, people who inject drugs, and people from countries where HIV is endemic).

### 2.3 Patients' Experiences With Current Therapy

**Current HIV risk reduction:** Among all respondents, condoms were the most commonly reported method or tool for HIV risk reduction, followed by having sex with partners of the same HIV-status (i.e., sero-sorting), then choosing lower risk activities such as being the insertive partner for anal intercourse. Sixty-four percent of people reported that these methods or tools addressed their HIV-prevention needs, while 36% reported they did not. A number of respondents cited an increase in pressure to have, or preference for, condom-less sex among gay men.

- *Condoms. Sero-sorting. Choosing lower risk activities. [30 yr, gay man, Alberta]*
- *high risk group [unknown, unknown, Manitoba]*
- *Condoms. Not always effective, not always desired. [26 yr, gay male, Nova Scotia]*
- *Most folks I engage in sex with prefer not to use condoms [30 yr, gay male, Ontario]*
- *I fall in the group with high risk indicators, inconsistent condom use, occasional STI occurrence, unknown or HIV+ (undetectable) status partners. [50 yr, gay male, Manitoba]*
- *Abstinence - not desirable (nor practical). "Insertive" partner (Top) - ok, but limited my sexual experience. Condoms - For me not desirable, as I find it very hard to maintain an erection while using condoms [50 yr, gay male, Manitoba]*
- *I'm a single guy who's used to condomless sex with a regular partner, so it's challenging to use/insist on condoms all the time, putting me at increased risk for infection. [31 yr, gay male, Ontario]*

**Fear and anxiety associated with sex:** Five of 7 PrEP-experienced people reported fear, anxiety, guilt and/or shame associated with sex, and any illnesses perceived to be acute HIV infection, prior to going on PrEP.

- *Before PrEP I was living in fear of "when" I would become HIV+, and if I did become HIV+ would I unknowingly infect someone else and how would I deal with the stigma associated with being HIV+ [50 yr, gay male, Manitoba]*
- *I found myself engaging in condomless sex with casual partners, especially when drinking. This led to stress and anxiety about HIV. It also caused upset in my relationship with my partner, as it disrupted our sex life when we needed to use condoms with each other as a result of me engaging in high risk sex with other people. I experienced guilt and shame around my sexual choices, because I did not want to put my partner at risk. [29 yr, trans queer man, Ontario]*
- *I have had some experiences of inconsistent (delayed) condom use that have worried me. [32, gay/queer male, Ontario]*
- *I was having condom-less sex regularly. I had a lot of anxiety from the moment I did it until I'd get tested. [37 yr, gay male, Ontario]*
- *I have multiple partners and I'm active in the kink community, so I often have group sex or consensually place myself in situations in which I'm vulnerable to my partner. I use protection almost always, but I'm very fearful that a slip up, condom breakage, or situation outside my control will result in seroconversion. I get anxious about acute HIV infection each time I get sick. [25 yr, gay male, Ontario]*

These feelings and states of mind were shared by some respondents who have not taken PrEP.

- *I've experienced significant anxiety over my HIV infection risk, which makes it not only difficult to enjoy sex as fully as I'd like to, but makes life in general more stressful. [31 yr, gay male, Ontario]*

**Considering Truvada for HIV PrEP:** Six out of 10 respondents who have not been on PrEP reported considering PrEP.

- *Anonymous sex with persons who may lie about their status and/or adherence to medications for treatment [26 yr, gay male, Nova Scotia]*
- *I like the medical science behind it; instead of covering up (i.e., condom) it actually provides medicine to warn off the virus [26 yr, gay male, Nova Scotia]*
- *Meeting people for casual sex who are on PrEP and do not want to have anal sex without a condom. [53 yr, gay male, Ontario]*
- *It adds to the repertoire of things I can do to stay HIV negative. I have been HIV negative and lived in the midst of the HIV epidemic as an out gay man for 30 years. It has not always been easy to do. PrEP could add an additional measure of protection. [53 yr, gay male, Ontario]*
- *Within the context of being in an open relationship and having sex with others... With an increase in condomless sex throughout the communities we have sex in, as well as in ongoing relationships with other dates, there can be pressure to have sex without condoms, which is unfortunate -- a) that pressure exists, b) that this is seen as a barrier to intimacy – but based on my current life circumstances and how that squares off with sexual decision-making, the incentives aren't there for me to begin PrEP at this time. [23, gay/queer male, Ontario]*

**Decision to take Truvada for HIV PrEP:** Five of 9 PrEP-experienced respondents reported inconsistent or no condom use for sexual intercourse, with two reporting that they “hate” condoms, and two reporting erectile problems associated with condoms. Some reported other life circumstances that caused them to decide on PrEP.

- *I'm very sexually active and hate condoms. So I was looking for a solution to have a safe sex without using condom and heard about the trial. [38 yr, gay male, Ontario]*

- *My partner and I opened our relationship, so I was starting to have casual sex with partners outside of my relationship [29 yr, trans queer man, Ontario]*
- *Despite successfully using condoms very consistently for over 20 years, I found it increasingly difficult to continue to do so. After a bout with depression, and possibly because I was approaching mid-life, I had more and more problems with erections. I am usually the insertive partner. So condoms were no longer a viable option to reduce my risk. I still wanted to do everything I could to avoid HIV while still enjoying a healthy sex life. Condoms worked perfectly well for me for over 20 years. But not with my new life circumstances. [46 yr, gay male, Quebec]*
- *I am in relationships where I do bareback, and I am in an open relationship. [42 yr, gay male, Ontario]*

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

The information in this section was gathered in the same means as described in section 2.1.

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

**Life changes associated with Truvada for HIV PrEP:** Overall, 78% (7/9) of PrEP-experienced respondents reported “extremely positive” or “positive” effects of PrEP on their health and well-being; the remaining 2 people reported “no effect.” Among those people who reported changes, people consistently cited lower anxiety, greater enjoyment of sex, and increased sense of safety, control and closeness in their sexual and/or intimate relationships. A minority of participants also reported other health promoting behaviours like accessing health services, and engaging in HIV risk reduction discussions with sex partners.

- *I am also more comfortable talking about safer sex practices with potential partners. I get tested for general health concerns relating to the medication, as well as for sexually transmitted infections more routinely than before taking Truvada for HIV PrEP. [29 yr, trans queer man, Ontario]*
- *Since I've been on PrEP, I have been in more regular contact with my physician, which has helped to address any other non-PrEP-related health issues much more quickly than otherwise would have been the case. I now get tested for HIV and all STIs twice as often as I used to--every 3 months. [46 yr, gay male, Quebec]*
- *My sex life got much better And I was really happy during year I was taking prep. Because I was feeling Safe [38 yr, gay male, Ontario]*
- *Anxiety over risk levels definitely affected my ability to bottom. The desire was there, but I often couldn't relax enough to make sex possible. I would also get anxious whenever I get sick - looking for a rash, thrush, checking my lymph nodes over and over. On PrEP I finally feel in control and as a result I can enjoy a full and rich sex life. It's also brought me closer to my partner. [25 yr, gay male, Ontario]*

Among respondents who had never taken Truvada for HIV PrEP, 80% (4/5) perceived that it would have an “extremely positive” or “positive” effect on their overall sense of health and well-being.

- *Would rather be on PrEP to provide maximum protection and peace of mind. Relying on condoms can be a barrier - to pleasure and intimacy. [31 yr, gay male, Ontario]*
- *Limitations and fears around testing make it challenging for people to actually know their status, and it would be helpful to have access to PrEP so that I feel adequately protected from HIV infection. This will increase my personal agency around sex and relationships, and will help release many years of anxiety and fear about becoming positive. [31 yr, gay male, Ontario]*
- *People who are bottoming and having difficulty with condom adherence, people who are having sex in communities with a high community viral load, people who are experiencing mental health and/or*

*chaotic substance use issues, people who are having commercial sex – this [PrEP] is an important intervention and should be provided free, at point-of-service-access, and in increased multidisciplinary care settings that heretofore don't sufficiently exist anywhere in Canada for these individuals.* [32, gay/queer male, Ontario]

- *Other than protection from HIV infection, I would say increased quality of life resulting from decrease in stress and anxiety of getting infected.* [31 yr, gay male, Ontario]
- *The feeling of protection that I get from PrEP has allowed me to enjoy sex more and more frequently, explore condomless sex safely with my primary partner, and eliminated my anxiety over illness as I no longer feel at significant risk of seroconversion. PrEP has changed my life.* [25 yr, gay male, Ontario]

**Truvada for HIV PrEP compared with other HIV risk reduction:** All 8 PrEP-experienced respondents cited advantages of PrEP over, or in association with, other HIV risk reduction strategies such as condoms, or only being the insertive partner during anal intercourse. Many reported feeling safer or more relaxed, that Truvada was much easier to adhere to than condom use, and that they no longer feared condom breaking during sex.

- *Truvada is amazing, It let me live my life just how I love to live, I couldn't get that much safe feelings even from using condoms because condoms may break but not Truvada* [38 yr, gay male, Ontario]
- *Condoms worked perfectly well for me for over 20 years. But not with my new life circumstances PrEP proved to be a great solution that fit my needs at this particular time. If PrEP had not been available to me for the past 3 years, I may very well have become infected.* [46 yr, gay male, Quebec]
- *It [PrEP] is at least as effective at reducing my HIV risk as condoms. I am as consistent with my PrEP use as I was with my condom use. So in both cases, my HIV risk is reduced in equal measure. However, it is much easier to be consistent about my PrEP use. I just take it with my vitamin every morning. I don't need to negotiate condom use in the heat of the moment. PrEP is much better in this way. Even if I missed a dose at some point, I'd still have very high levels of protection. But I don't use a condom, I have zero risk reduction for that time.* [46 yr, gay male, Quebec]

**Impact of Truvada for HIV PrEP on sexual and intimate relationships:** All PrEP-experienced respondents reported a better sex, life, greater ease with sexuality or sexual expression, or improved relationships with sexual or intimate partners.

- *Since being on PrEP, my anxiety over sex has largely been eliminated and I personally have learned that the stigma toward HIV+ people can be eradicated, it has for me!* [50 yr, gay male, Manitoba]
- *Absolutely made my sex life better and I was happier* [38 yr, gay male, Ontario]
- *Positive - I am comfortable having the sex life that I want to have, without worrying about getting HIV and putting my partner at risk for getting HIV. I am less afraid of having sex with new partners, I am having more sex than before, I am having more conversations about PrEP and HIV than before.* [29 yr, trans queer man, Ontario]
- *My primary partner and I have explored condomless sex, which I previously assumed to be something that I would never safely experience in my lifetime.* [25 yr, gay male, Ontario]
- *PrEP allows me to connect and be intimate with my sexual partner in a way that was not possible with condoms. A big part of that is that the fear of HIV has gone away. You have to use a condom in the heat of the moment. But I take my pill in the morning with breakfast. So "HIV" isn't in the room with us when we're being intimate.* [46 yr, gay male, Quebec]
- *I am slightly less sexually active - I communicate more about my activity - I am enjoying myself a lot more. It helps me to relax even more, even with the recent news from Dr. Knox about someone seroconverting while taking PrEP, I can still relax a bit more. I'm able to be a bit more closer to those I play with.* [42 yr, gay male, Ontario]

- *Yes made it better Because I was able to have sex with [HIV] positive people too. [38 yr, gay male, Ontario]*
- *I no longer have anxiety with sex, I enjoy sex more. I couldn't keep an erection with condoms and so I don't need to worry about that either. I also like not having to ask guys their HIV status. Yes, my sex life is better, my sex is better, more intimate, more fun, less anxiety about going soft with condom use and my friends no longer worry about my sexual behaviors, now that I am protected from HIV with PrEP. [37 yr, gay male, Ontario]*

One survey respondent living with HIV commented on the effect of PrEP on the psychological well-being of his HIV-negative sexual partners.

- *I already have HIV, but practice safe sex with HIV- sexual partners. PrEP provides an opportunity for my HIV- partners to feel more confident that they are not at risk in case the condom breaks... [51 yrs, bisexual male, Ontario]*

**Truvada side-effects:** Two of 9 pre-experienced reported side effects. One reported a “bit of headache and nosia [sic] but only during the first few weeks.” The other reported “nosia [sic], vometin [sic] but not too bad, headache.” Among people who had no experience taking Truvada for HIV PrEP, an equal number would be willing, and not willing, to experience mostly minor side effects.

- *Yes [I would be willing to experience side effects.] I understand I need to get tested regularly to monitor side effects (i.e. kidney function). My understanding is that the medication is well-tolerated and that a small proportion will experience some minor, short-term side effects like nausea. [31 yr, gay male, Ontario]*

## Section 4 — Additional Information

**Truvada experience and cost coverage:** Of people who had ever taken Truvada for HIV PrEP, 45% obtained it as a participant in a clinical trial, one third through private insurance, and one third through a public drug program—with at least one person obtaining it through multiple avenues. None of the survey respondents reported paying for Truvada out-of-pocket. One person expressed concerns regarding being unable to afford PrEP when the clinical trial in which he is enrolled comes to an end:

- *I work at a small nonprofit, so I don't have health insurance and my salary is quite low. I can't afford PrEP out of pocket, nor can I afford private insurance. Probably when my clinical trial ends I will import a generic form of PrEP from overseas by having it shipped to the USA and crossing the border to pick it up each month. [25 yr, gay male, Ontario]*

CTAC notes with concern that importation as described above is arguably contrary to the *Food and Drugs Act*, in practice highly dependent on border service agent discretion, only an option for people who are legally entitled to leave and return to Canada, and might lead to gaps in treatment and clinical follow up for the respondent (or others in similar circumstances).

One respondent expressed the health equity-related concerns related to the cost of and access to Truvada for HIV PrEP:

- *I'm also worried that disparities in the health care system (ie. people with privilege having private coverage) will mean that people who don't really need the intervention (ie. "Tops on PrEP") will get it while people who are economically and socially marginalized will have difficulty achieving access, either through coverage or a lack of point-of-care interventions. [32, gay/queer male, Ontario]*