

### Truvada is Approved for HIV Treatment and Prevention

Truvada is an oral fixed-dose combination tablet containing two HIV antiretroviral agents, emtricitabine and tenofovir disoproxil fumarate. Health Canada issued Truvada a Notice of Compliance (NOC) in 2006, for use in combination with other HIV antiretroviral agents, for the treatment of HIV-1 infection in adults. Currently, all public drug plans in Canada include Truvada for HIV treatment.

In February 2016, Health Canada approved Truvada, in combination with safer sex practices, for HIV pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infections in HIV-negative adults at high risk. As of March 2017, only two public plans (Quebec and the Non-Insured Health Benefits program for First Nations and Inuit) include Truvada for HIV PrEP. Other public drug plans will soon begin or have begun the process of deciding whether to include Truvada for HIV PrEP.

*CTAC advocates for timely, affordable and equitable access to medications and other tools to treat, diagnose and prevent HIV and hepatitis C in Canada.*

*This Policy Brief provides detailed information, with links to source documents, about Truvada and its process for regulatory approval and public drug plan listing—for the treatment of HIV infection and for HIV PrEP.*

*The information is current as of March 2017 and was extracted from [CTAC's Treatment Map \(TxMAP\)](#) database and other online resources as indicated.*

### Truvada Medication Information

Brand Name	Manufacturer	Generic Name	Type of Medication	Product Monograph	Indication	CATIE Resources	Health Canada NOC	Common Drug Review Final Recommendation
Truvada	Gilead Sciences	emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)	HIV anti-retroviral co-formulation; oral tablet	Revised 23 February 2016 	Treatment of HIV-1 Infection	<a href="#">Treatment</a>	6 January 2006 	17 December 2008 
					Pre-Exposure Prophylaxis of HIV-1 Infection	<a href="#">PrEP</a>	26 February 2016 	26 August 2016 

### The Price of Truvada

Truvada is a brand name drug legally protected by patents which give Gilead Canada the exclusive right to sell Truvada in Canada until July 2017. The retail cost of taking one pill of Truvada every day is between \$800 and \$1000 per month, depending on where someone lives and purchases medication. This is the cost that a person who does not have prescription drug insurance—either public or private—would pay at the pharmacy. To make drugs financially accessible to more people, the federal, provincial and territorial governments in Canada have set up public drug insurance plans to benefit people who are eligible and would not otherwise be able to afford the cost of essential medications. The public drug plans enter into agreements with pharmaceutical manufacturers to pay significantly less than the retail cost when they buy drugs.

# Following the Regulatory Pathway for Truvada as PrEP

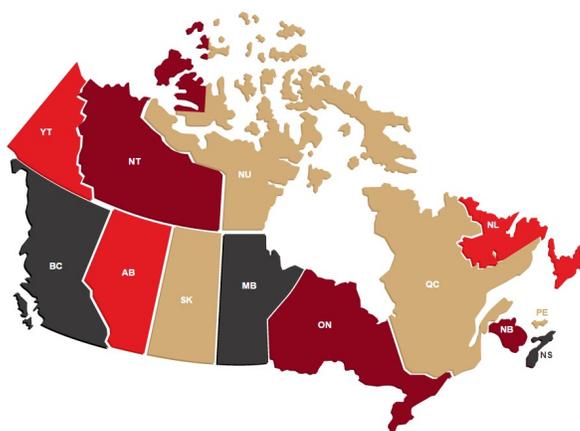
(March, 2017)

## Public Listing of Truvada for Treatment of HIV

Formulary & Listing Status	Formulary Listing Date	Formulary Listing Category	Drug Program Name
Alberta			
YES	N/A	R	SHCDP
British Columbia			
YES	N/A	FB	BC-CfE
Manitoba			
YES	02/29/2009	SA	EDSP
New Brunswick			
YES	06/29/2009	FB	Plan U
Newfoundland & Labrador			
YES	05/01/2008	SA	N/A
Northwest Territories			
YES	04/01/2008	FB	EHB++
Nova Scotia			
YES	N/A	FB	N/A
Nunavut			
YES	04/01/2008	FB	EHB
Ontario			
YES	09/04/2007	GB	FAM
Prince Edward Island			
YES	03/01/2009	FB	AHDP
Quebec <sup>1</sup>			
YES	10/01/2006	FB	N/A
Saskatchewan			
YES	04/01/2007	EDS	N/A
Yukon			
YES	09/11/2009	E	CDP+
<b>Federal Drug Plans</b>			
Canadian Forces Health Services (CFHS)			
YES	N/A	RB	N/A
Correctional Service Canada (CSC)			
YES	N/A	OB	N/A
Interim Federal Health Program (IFH)			
YES	N/A	Per provincial formulary	Per provincial formulary
Non-Insured Health Benefits (NIHB) <sup>1</sup>			
YES	N/A	OB	N/A
Veterans Affairs Canada (VAC)			
YES	N/A	SB	N/A

### Legend: Formulary Listing Category

E	Exception
EDS	Exception Drug Status
FB	Full Benefit
GB	General Benefit
OB	Open Benefit
R	Restricted
RB	Regular Benefit
SA	Special Authorization
SB	Standard Benefit



### Legend: Drug Program Name

AHDP	AIDS/HIV Drug Program
BC-CfE	BC Centre for Excellence in HIV/AIDS Drug Treatment Program
CDP+	Chronic Disease Program or the Pharmacare Program (for seniors 65 and over)
EDSP	Exception Drug Status Program
EHB	Extended Health Benefits Program
EHB++	Extended Health Benefits for Specified Disease Conditions Program, the Extended Health Benefits for Seniors' Program, and the Métis Health Benefits Program
FAM	Medication must be prescribed by an approved physician registered under the Facilitated Access Mechanism
Plan U	HIV/AIDS plan (patient must be registered by a New Brunswick Infectious disease specialist)
SHCDP	Specialized High Cost Drug Program

### Note

<sup>1</sup>The Quebec and NIHB drug plans currently include Truvada for HIV PrEP. Neither plan has reviewed Truvada for HIV PrEP. Each plan includes Truvada as a full or open benefit, without additional restrictions or criteria.

# Following the Regulatory Pathway for Truvada as PrEP

(March, 2017)

3

## Three Steps for Public Coverage of HIV PrEP

About [10 million people](#) in Canada get prescription drugs through public drug plans—federal, provincial and territorial. Each public drug plan—18 in all—is different from the others. ***The patchwork of 18 public drug plans results in unequal and inconsistent prescription drug access for people in Canada.*** Each plan has its own administrative rules, procedures, timelines and decision-makers. Each operates within its own political and budgetary context. People eligible under public drug plans do not necessarily get drugs for free. A person may have to pay some of the cost, through a co-payment or deductible, or pay the pharmacy up-front and make a claim for reimbursement. The plans do not all provide the same range of medications—some include fewer, some more.

The charts on page 2 show some of the differences among provincial plans that often affect people's access to drugs. Every public plan currently lists Truvada to treat HIV. But not all plans listed it on the same date, and the formulary listing category and drug program used to provide or restrict access vary widely among different plans. As a result, there are many different pathways to Truvada for treatment under public drugs plans in Canada. Only two plans include Truvada for HIV PrEP. Health Canada approved Truvada for HIV PrEP in February 2016. But not all drugs approved by Health Canada get listed (in other words, included) on public drug plans. ***After a drug is approved for use by Health Canada, a manufacturer must successfully complete a three-step process to get a drug listed on public drug plans. This process can take many months, or years in exceptional circumstances. In March 2016, Gilead Canada's application for Truvada as HIV PrEP was accepted into step one of the process.***

### Step 1: Common Drug Review

In March 2016, the Canadian Agency for Drugs and Technologies in Health (CADTH) accepted Gilead Canada's application for Truvada as HIV PrEP to the Common Drug Review (CDR) process. Other than Quebec, all provincial, territorial and federal public drug programs participate in the CDR. The CDR involves a review and assessment of a new drug by comparing it with existing drugs used to treat the medical condition. The CDR is completed by a sub-group of CADTH called the Canadian Drug Expert Committee (CDEC). Taking into account the new drug's therapeutic advantages and disadvantages, and its cost-effectiveness based on the price submitted by the drug manufacturer, CDEC makes a non-binding listing recommendation to the participating public drug plans.

***In August 2016, CDEC recommended that public drug programs reimburse Truvada for HIV PrEP, so long as two conditions were met. The first condition recommended that prescribers be experienced in the treatment and prevention of HIV and that PrEP be prescribed as part of a sexual health program. The second condition called on Gilead to reduce the price of Truvada.***

### Quebec Drug Review

Quebec does not participate in the CDR. It has its own health technology assessment agency (INESSS) and process. Similar to the CDR, INESSS assesses the clinical advantages and costs of medications and issues recommendations concerning their listing on Quebec's public drug plan. Although Quebec's public drug plan already includes Truvada for HIV PrEP, INESSS has only assessed Truvada for treating HIV-1 infection.

***It is not clear whether INESSS will assess Truvada for HIV PrEP. However, given the HIV burden in Quebec and the fact the province is ahead of other provinces in PrEP preparedness—listing, prescribing and interim guidance—CTAC expects Gilead Canada will be prepared to submit Truvada for HIV PrEP to INESSS for assessment.***

# Following the Regulatory Pathway for Truvada as PrEP

(March, 2017)

4

## CTAC Patient Input to the Common Drug Review

Patient input submissions ensure drug regulatory bodies are informed about public interest in new medications. CTAC, the AIDS Committee of Toronto and Maggie's: The Toronto Sex Workers Action Project each held community consultations and submitted patient input reports to CDEC.

CTAC's submission was based on an online consultation with 21 respondents who either had used PrEP or were interested in using it. In addition to discussing the value of PrEP as a prevention tool, respondents highlighted an array of psycho-social benefits of using PrEP. Respondents who had taken PrEP spoke of the impact PrEP had on their sex life including lowering their anxiety about HIV, providing them with a sense of safety and control, and increasing enjoyment and intimacy with their sexual partners. Several respondents also described using PrEP as increasing their involvement in sexual health care and said they felt more comfortable to discuss sexual health with their sexual partners after starting PrEP. Respondents who had not used PrEP were interested in the medication as a prevention tool and a means of improving their overall well-being. Respondents had relatively little concern about the safety of the medication itself. However, many were concerned that the price of Truvada created a barrier to accessing PrEP and could reinforce long-standing health inequities.

## Step 2: pan-Canadian Pharmaceutical Alliance

Instead of negotiating separately with a drug manufacturer, public drug plans in Canada rely on the pan-Canadian Pharmaceutical Alliance (pCPA) to review drugs and negotiate pricing on their behalf. The pCPA uses its collective bargaining power to get a better deal than the plans could get negotiating separately. A successful negotiation between the drug manufacturer and the pCPA leads to a Letter of Intent (LOI).

The pCPA is in the process of developing rules, procedures and guidelines for negotiations, but it is currently not clear how drugs move from the queue into active negotiations. The pCPA also does not yet publish process metrics and it is impossible to know how long negotiations might last. In July 2016, the pCPA Office started preparing its file on Truvada for HIV PrEP. As of 31 January 2017, the pCPA reported that there were 38 negotiations underway; Truvada as PrEP was not listed as under negotiation.

Once Truvada as PrEP is selected for active negotiations, each province will decide their involvement in the negotiations. While Quebec and NIHB already list Truvada as PrEP on their formularies, both are members of the pCPA and may choose whether or not to participate in the negotiation. Gilead will prepare a submission to the pCPA for consideration, including a listing price and a budget impact analysis. If the participating public drug plans and Gilead are able to reach an agreement to list Truvada for HIV PrEP—an outcome that is not certain—the pCPA and Gilead Canada will sign an LOI setting out agreed-to matters related to drug pricing and cost to the public plans. In the next step in the regulatory approval and listing process Gilead will try to enter into individualized agreements with the separate public drug plans.

## CanPrEP: Providing Community Input to the pCPA

CanPrEP is an alliance of community and community-minded individuals and organizations who have come together to promote understanding about, access to and uptake of HIV PrEP in Canada. As a group, CanPrEP submitted input to the pCPA to ensure community needs were considered in price negotiations and CTAC played a leading role developing these submissions.

CanPrEP made an initial submission to the pCPA in August of 2016. This submission argued for public listing of Truvada as PrEP based on its efficacy, its novelty as the first HIV prevention drug in Canada and its potential to play a significant role in public health efforts against a disease that principally affects groups experiencing health inequities. Broad public listing was supported with background research on the cost-effectiveness of PrEP. The submission also highlighted potential for reducing the current price of Truvada in negotiations with the manufacturer given the significant earnings Gilead has derived from Truvada as HIV treatment, and expenditures by publicly funded organizations on PrEP research. The letter also argued for the pCPA to prioritize negotiations with the manufacturer to expedite wider availability of PrEP and to prevent further HIV infections.

In January 2017 CanPrEP made a second submission to the pCPA to address the conditions in CDEC's final report. In particular, CanPrEP felt it necessary to address the condition that PrEP be, "*provided in the context of a sexual health program by a prescriber experienced in the treatment and prevention of HIV-1 infection.*" CanPrEP recommended listing PrEP as an open benefit on public drug plan formularies as a means of making best use of the existing pool of healthcare providers capable of prescribing and monitoring Truvada for HIV PrEP. The submission also argued against a narrow interpretation of the CDEC condition that would place responsibility for providing PrEP on specific providers- namely sexual health clinics and HIV specialists- as this could create unnecessary workload for services that are already overburdened, would limit patient access to PrEP, and is not clinically necessary. Successful inclusion of a broad range of healthcare providers could be achieved with appropriate professional development and access to guidance, resources and other tools that support optimal patient outcomes.

## Step 3: Price Listing Agreement

The pCPA operates on the assumption that each public drug plan that participates in a drug negotiation will enter into a contract with the drug manufacturer to list the drug in a timely manner and according to the LOI. This contract is called a Price Listing Agreement (PLA). However, in practice this does not always occur, for two reasons. First, the pCPA process and LOI are not binding on the public drug plans; each plan retains the power to decide whether to list a drug. Second, manufacturers may focus their attention on entering into PLAs with plans with the greatest number of people in need of their drug (i.e., where there is the greatest potential for profit). British Columbia, Ontario and Quebec have a relatively high number of people living with HIV and new HIV cases every year compared with other federal, provincial and territorial public drug plans. ***Given the uncertain timelines of the pCPA and PLA processes, and the unique circumstances of Truvada as the first HIV prevention drug, we are not able to estimate which public drug plans will begin listing Truvada as PrEP and when those listings will occur.***

# Following the Regulatory Pathway for Truvada as PrEP

(March, 2017)

6

## Resources

### PrEP Regulatory Documents

- **Truvada Product Monograph**- [http://www.gilead.ca/pdf/ca/truvada\\_pm\\_english.pdf](http://www.gilead.ca/pdf/ca/truvada_pm_english.pdf)
- **Health Canada Notice of Compliance for Truvada as PrEP**- <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/rds-sdr/drug-med/rds-sdr-truvada-187173-eng.php>
- **CTAC Patient Group Input Submission to CDEC**-<http://ctac.ca/uploads/treatmentaccessnews/CTAC-Submits-Patient-Group-Input-on-HIV-PrEP-to-CADTH.pdf>
- **CDEC Final Recommendation on Truvada as HIV Pre-Exposure Prophylaxis**- <http://ctac.ca/uploads/treatmentaccessnews/CDEC-Recommends-Reimbursement-of-Truvada-for-HIV-PrEP-Under-Public-Drug-Plans.pdf>
- **CTAC's Preliminary Analysis of CDEC Recommendations**- <http://ctac.ca/uploads/treatmentaccessnews/CTACs-Preliminary-Analysis-of-CDEC-Recommendation-on-Truvada-for-HIV-PrEP.pdf>
- **CanPrEP First Submission to the pCPA**- <http://ctac.ca/uploads/treatmentaccessnews/CanPrEP-%20Submits-%20Recommendations-on-Truvada-for-HIV-PrEP-to-pCPA.pdf>
- **CanPrEP Supplemental Submission to the pCPA**- <http://ctac.ca/uploads/treatmentaccessnews/CanPrEP%20pCPA%20Supplement%20Final.pdf>

### General Regulatory Resources

- **CTAC Website**- <http://ctac.ca/home>
- **Treatment Access Map**- <http://ctac.ca/resources/treatment-access-map>
- **Canadian Agency for Drugs and Technology in Health (CADTH)**- <https://www.cadth.ca/>
- **pan-Canadian Pharmaceutical Alliance (pCPA)**- <http://www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>
- **Institut National d'Excellence en Santé et en Services Sociaux (INESSS)**- <https://www.inesss.qc.ca/en/publications/inessss-guides.html>

### PrEP Resources

- **CATIE PrEP Resources**- <http://www.catie.ca/en/prep>
- **AIDS Committee of Toronto PrEP Resource**- <http://actoronto.org/prep>
- **The Sex You Want**- <http://thesexyouwant.ca/prep/>
- **Get PrEPed**- <http://www.getpreped.ca/>
- **PrEP & Women: What You Need to Know**- <http://www.whai.ca/ModuleFile?id=181>
- **PrEP in the Context of Sex Work**- <http://triple-x.org/safety/prep/#prepincontext>
- **PrEP - Canada: Rethinking HIV Prevention/Repenser la prévention du VIH**-<https://www.facebook.com/groups/prepcanada/>
- **PrEP Facts (US)**- <http://prepfacts.org/>



[www.ctac.ca](http://www.ctac.ca)

P.O. Box 203, Suite 612 • 555 Richmond Street West • Toronto, ON M5V 3B1  
GTA: 437-222-CTAC (2822) • Fax: 416-410-1369 • Toll Free: 1 (877) 237-CTAC

