

Truvada for HIV PrEP: The pathway to market & public cost coverage in Ontario, as an example

Prepared as background for:

PrEP in the Context of Sex Work: Possibilities and limitations

May 2016

Glenn Betteridge, Policy researcher

Terry Santoni, Program assistant





Canadian Treatment Action Council

- CTAC is Canada's national civil society organization addressing access to treatment for people living with HIV and hepatitis C.
- CTAC meaningfully engages community members, service providers, policymakers and researchers to identify and implement policy and program solutions.



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Objectives

1. Increase our knowledge of Truvada for PrEP in the Canadian context
2. Map out the “pathway” to increased access to PrEP for people in **Ontario**
 - ▶ Focus on public drug plan coverage
3. Highlight treatment access issues
4. Highlight national and **Ontario** awareness, action and advocacy
5. Build CTAC’s awareness and knowledge of your issues and concerns

Truvada for PrEP approved

- **Health Canada approved Truvada for HIV PrEP on 26 February 2016**
 - ▶ Gilead can legally market Truvada for PrEP
 - ▶ First step to greater access
 - More prescribing
 - More cost-coverage under **private and public drug insurance plans**
- Market access process unfolding faster than anyone expected
 - ▶ **Are we PrEPared?**



Cost, access & cost-coverage

- Cost-coverage: Who pays currently?
 - ▶ **Quebec's** universal public drug program and **Non-Insured Health Benefits** cover Truvada for PrEP
 - Private insurers in Quebec must cover the cost too
 - Some people in Ontario have had it covered under Trillium Drug Program (shhhhh!)
 - ▶ Other people currently taking PrEP
 - Pay out-of-pocket and/or “import” generic
 - Covered under private insurance
 - Not all insurance plans have covered PrEP
 - Enrolled in a study or clinical trial



Cost in Ontario, an example

- In Ontario, if you bought Truvada for PrEP at a pharmacy, approximately how much would you have to pay each month?

- a) \$600 per month
- b) \$800 per month
- c) **\$1000 per month**
- d) \$1200 per month

$(\$32.60 \text{ per pill} \times 365 \text{ days} / 12 \text{ months} = \$991.58 + \$12 \text{ dispensing fee} = \textbf{\$1,003.58})$

PAYING
FOR PrEP





The Pathway to Public Listing



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The “pathway”

- “Pathway” to public drug plan cost-coverage is long and complex
 - ▶ “Pathway” = **Process** for the approval, marketing, and cost-coverage of prescription drugs
 - ▶ Step-by-step, many months, 1000s pages of submissions and evidence, many decision-makers along the way to **public** drug coverage
 - ▶ Process is driven by Gilead (Truvada patent-holder)
 - ▶ Involves federal, provincial and territorial authorities, drug experts, and “patient groups”

Approval & public listing



Strengthening treatment, care and support
for people living with HIV and HIV/hepatitis C
co-infection in Canada



HOME ABOUT US OUR ISSUES RESOURCES GET INVOLVED CONTACT

APPROVAL AND PUBLIC LISTING OF DRUGS IN CANADA - THE COMMON DRUG REVIEW



This short yet detailed account of how drugs become available in the Canadian Market place is a helpful crash course in understanding Canada's very complex drug approvals mechanisms.

<http://www.ctac.ca/resources/videos/approval-and-public-listing-of-drugs-in-canada---the-common-drug-review>



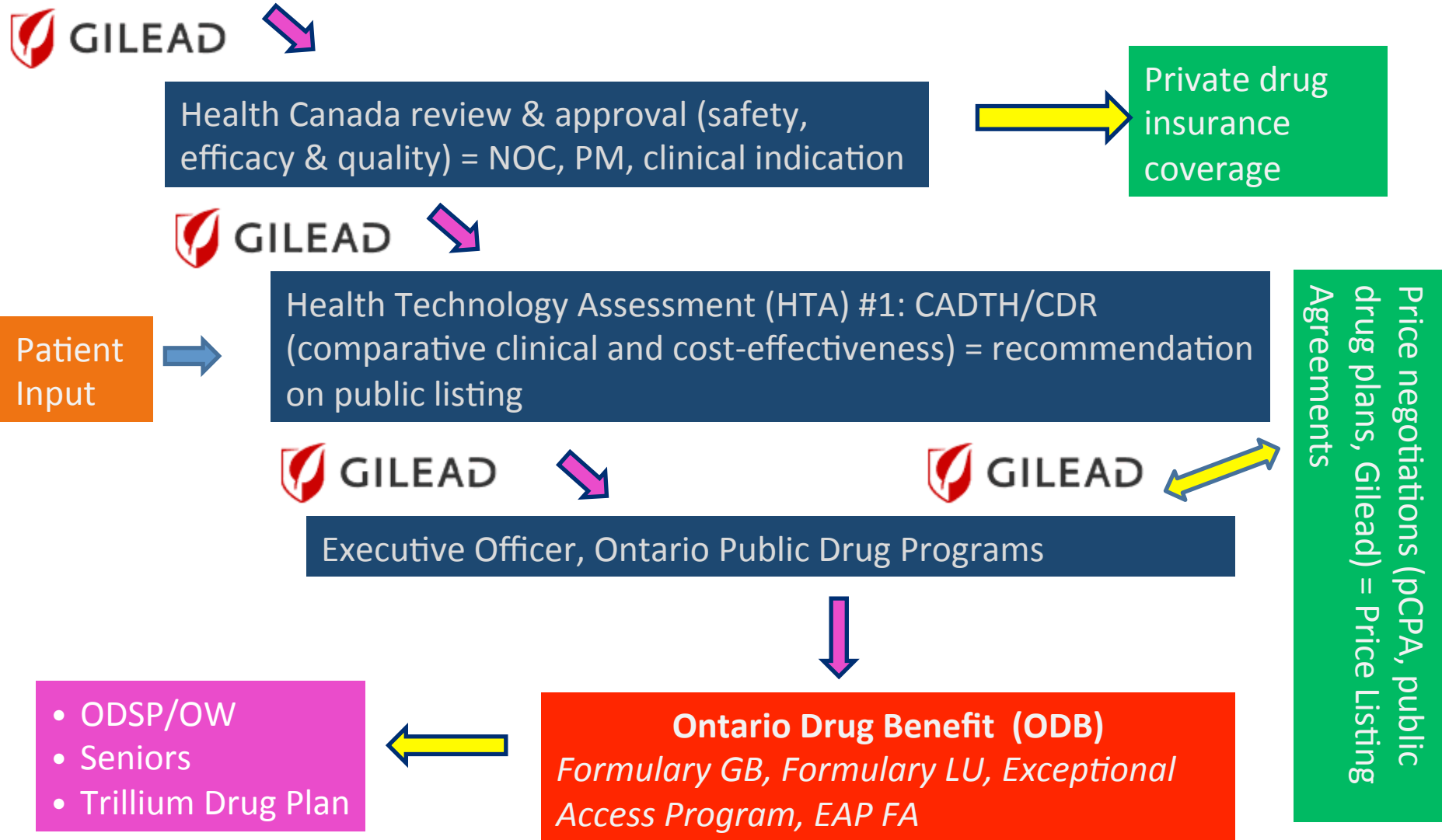
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Truvada “pathway” for Ontario

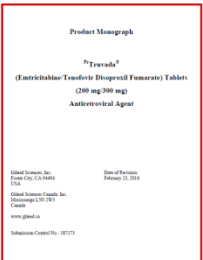
- Steps along the pathway determine private and **public drug plan access**
 - ▶ who gets Truvada as PrEP
 - ▶ under what government program
 - ▶ according to which rules and procedure
 - ▶ who pays, when, and how much



Truvada “pathway” for Ontario



Truvada “pathway” for Ontario



Ontario Drug Benefit (ODB) Program



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Truvada for PrEP Timeline

2015

★ Open Letter to Gilead (April)

★ Gilead Applies
For NOC (August)

2016

★ Gilead Applies to CADTH/CDR (January)

★ Health Canada Issues NOC
(February)

★ CADTH/CDR Patient Group
Submissions (March)

★ CADTH/CDR Application Accepted
(March)

★ CDR/CDEC Recommendation
(?August?)

★ pCPA—Gilead Negotiations?
(August to December 2016?)

★ F/P/T Public Drug Plan Listing?
(starting December to 2017+????)

2017

★ Gilead's Truvada Patent Expires (July)



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Health Canada Review & Approval



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Health Canada Review



Health Canada Review

- Health Canada reviews
 - ▶ Drug safety and efficacy (human clinical trial data)
 - Specific medical condition, with a particular drug, in a specific population, in specific circumstances
 - ▶ Manufacturing quality
 - ▶ Essential info in scientific and marketing materials
 - ▶ And decides whether to **approve drug for sale in Canada**



Notice of Compliance (NOC)

- Notice of Compliance (NOC) issued by Health Canada if drug “approved”

- ▶ Approved for a specific clinical indication

The screenshot shows a 'Notice of Compliance Information' form. It includes a search bar, a table of links (Search, NOC, Frequently Asked Questions, NOC, NOC, NOC), and a list of fields: NOC Number (2010-03-08), Manufacturer (ISLAND SCIENCES CANADA INC.), Product Type (Prescription Pharmaceutical), NOC with Conditions (No), Submission Type (Supplement to a New Drug Submission (NDS)), Reasons for Approval (For use in combination with safer sex practices for Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk), Submission Class (Other), and a footer (Page 1 of 1, T0100000).

- Clinical trial data reviewed determines the **clinical indication**

- ▶ medical/scientific basis for prescribing
 - Drug prove safe and effective **in whom**, for **what medical condition**, at what **dose**, and under which **circumstances**

Truvada Product Monograph



UPDATED 23 February 2016, to include new indication for HIV PrEP

http://www.gilead.ca/pdf/ca/truvada_pm_english.pdf



Truvada's HIV PrEP indication



- Product monograph (PM) reviewed and approved as part of HC review leading to NOC
 - ▶ factual, scientific document on the drug
 - ▶ devoid of promotional material
 - ▶ describes the properties, claims, **indications for clinical use**, and **conditions of use** for the drug
 - ▶ any other information that may be required for optimal, safe, and effective use of the drug
- Indication(s) for clinical use
 - ▶ indication aka “label”
 - ▶ on-label *versus* off-label prescribing
 - ▶ public and private drug insurance plans normally cover only **on-label prescribing** (i.e., for the indication)



Daily Truvada for PrEP: According to Health Canada



- Pre-Exposure Prophylaxis (PrEP) of HIV-1 Infection (see PM, page 3-4)
 - ▶ daily
 - ▶ in combination with safer sex practices
 - ▶ to reduce risk of sexually acquired HIV-1 infection
 - ▶ in adults at “high risk” (i.e., risk assessment required)
 - Risk factors set out in Product Monograph



Daily Truvada for PrEP: According to Health Canada



- Following factors **may** help to identify a **person at high risk of HIV infection**:
 - ▶ partner(s) known to be HIV-1 infected, **or**
 - ▶ engages in sexual activity within a high prevalence area **or** social network, **and** one or more of the following:
 - inconsistent or no condom use
 - diagnosis of sexually transmitted infections
 - exchange of sex for commodities (e.g., money, food, shelter, drugs)
 - use of illicit drugs or alcohol dependence
 - incarceration
 - partner(s) of unknown HIV-1 status with any of the factors listed above



Daily Truvada for PrEP: According to Health Canada



- When prescribing Truvada for HIV PrEP, **healthcare providers must:**
 - ▶ Prescribe as part of **comprehensive HIV prevention**, because Truvada not always effective
 - ▶ **Counsel** about need for **strict adherence**
 - ▶ Confirm **HIV 1-negative status** through diagnostic testing prior to prescribing
 - ▶ **Screen for HIV-1 every 3 months**



Clinical indications

- Clinical indication shape next steps along the pathway
 - ▶ Health Technology Assessment / Pharmacoeconomic review
 - **Comparative clinical benefit** of drug versus other approved drugs for medical condition
 - **Cost-effectiveness and public plan budget impact**



- ▶ Price negotiations & public drug plan listing decisions
 - Will drug company **reduce the price**? How much?
 - **Can plan afford** drug for all the people who need it (i.e., for whom it can safely be prescribed and will be effective)?



Private Insurance Coverage



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Truvada “pathway” for Ontario



Private insurance plans

- Coverage for Truvada for PrEP depends on person's **insurance plan** (not the insurance company)
 - ▶ An insurance plan is a **contract**
 - ▶ **Group** plan: Contract between **insurance company** and a **specific employer** (for example), for the benefit of group members (i.e., **employees**)





Health Technology Assessment: Common Drug Review (CDR)



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Truvada “pathway” for Ontario



CADTH Common Drug Review

- Common Drug Review ([CDR](#))
 - ▶ Canadian Drug Expert Committee ([CDEC](#)) reviews and recommends brand name prescription drugs for public drug plan cost-coverage
 - ▶ **CDEC reviews clinical, economic, and patient** and health care provider **evidence**
- Will **CADTH “speed up”** process for Truvada for PrEP?
 - ▶ First drug to prevent HIV.... Important breakthrough for individual and public health



Truvada “pathway” for Ontario



CADTH Evidence Driven.

[illegible]

input submit

28 March 2016

Truvada

Brand name	Generic name
Truvada	Emtricitabine/tenofovir disoproxil fumarate
Project Number	

PATIENT INPUT

The experiences and feedback from patients is key in informing the recommendations CADTH makes to publicly fund drug plans throughout Canada.

You can learn more about the Common Drug Review via [this engaging video produced by CTAC](#).

UPCOMING CTAC PATIENT GROUP INPUT CONSULTATIONS:

TRUVADA AS PREP
Date to be determined
Sign up below to be notified
*Name


RESPONSE from CADTH: Clarifying "Patient Group" for submissions on Truvada as PrEP

CADTH has responded, as follows: "...we define a patient group as an organized group that represents patients with a specific disease or condition, or collection of diseases / conditions. A group will typically have members that are patients, and/or patients' family members, and have a public face, such as a website or Facebook page."

CTAC had asked CADTH for clarification about who could be a "patient group" specifically in the context of CADTH's call for patient group input into the Common Drug Review process evaluating Truvada for PrEP. CADTH did not directly address the issue of whether HIV-negative people (taking PrEP or who might want to take PrEP) are "patients." Truvada is the first drug for HIV prevention that CADTH will consider. CADTH's Canadian Drug Expert Committee will recommend whether the cost of Truvada for HIV PrEP should be covered under public drug plans and, if so, for whom.

Glenn Betteridge
Thursday at 5:42pm

CDEC recommendation



**CEDAC FINAL RECOMMENDATION
and
REASONS for RECOMMENDATION**

TENOFOVIR/EMTRICITABINE
(Truvada™ - Gilead Sciences Canada, Inc.)

This recommendation is superseded by the CEDAC recommendation for this drug and indication dated December 17, 2008.

Description:
Truvada™ is a fixed dose combination of two nucleoside/nucleotide reverse transcriptase inhibitors that is approved for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years of age and older.

Dosage Forms:
Tablet containing emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Truvada™ be listed as an alternative for the initial phase of treatment of adult patients with HIV infection who have experienced intolerance or adverse events with other nucleoside combinations including lamivudine in combination with zidovudine, abacavir, stavudine or didanosine and, who have not developed virologic failure or clinical progression on initial antiretroviral therapy.

Reasons for the Recommendation:

1. The Committee considered the data from one open label randomized controlled trial (RCT) of 48 weeks duration in treatment naïve patients that compared a regimen of zidovudine, lamivudine and efavirenz, against a combination of tenofovir, emtricitabine and efavirenz. The latter was associated with statistically significant improvements in virologic response (HIV-1 RNA levels <400 or <50 copies/mL). In part, this benefit may have resulted from the open-label design of the trial and the fact that more patients in the zidovudine/lamivudine arm discontinued therapy and were classified as treatment failures. There were no statistically significant differences between the two treatments in the occurrence of virologic failure or viral resistance.
2. There were fewer withdrawals due to adverse effects in the tenofovir/emtricitabine arm and this was primarily due to a lower incidence of anemia.
3. Truvada™ costs \$25.05 per day, which is more costly than other nucleoside combinations and combination products (eg. lamivudine/zidovudine costs \$19.51 per day). A

Common Drug Review

CEDAC Meeting – September 20, 2006
Notice of CEDAC Final Recommendation – October 25, 2006

Page 1 of 2

Canadian Drug Expert Committee (CDEC)

- reimbursement recommendations and advice
 - ▶ do not bind participating public drug plans
- CDEC/CADTH sends its “file” on the drug to each participating public drug plan
 - ▶ e.g., Ontario, CSC, NIHB, etc...

CDEC Timetable for Truvada

CADTH			
Common Drug Review Project Status Report			
Brand Name:	Truvada		
Non-proprietary Name:	emtricitabine/Tenofovir Disoproxil Fumarate		
Applicant:	Gilead Sciences Canada Inc.		
Indication(s):	HIV-1 infection, pre-exposure prophylaxis		
Project Type:	Submission	Date NOC Issued ¹ :	2016-Feb-26
Date Received:	2016-Mar-03	Application Fee Schedule ² :	Schedule B
Key Milestone ³	Target Date	Actual Date	Comments
Application accepted for review	2016-Mar-17	2016-Mar-17	- Review has been initiated 2016-Mar-18
Patient group input received ⁴	2016-Mar-28		- Call for patient input posted on 2016-Feb-04 - Patient group input deadline: 2016-Mar-28
Patient group comments on input summary received			
Draft CDR review report(s) sent to applicant	2016-Jun-02		
Comments from applicant on draft CDR review report(s) received by CADTH	2016-Jun-13		
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2016-Jun-20		
CDR review team's comments on draft CDR review report(s) sent to applicant	2016-Jul-08		
Canadian Drug Expert Committee (CDEC) meeting	2016-Jul-20		
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2016-Jul-27 to 2016-Jul-29		

CDEC meeting:

20 July 2016

CDEC recommendation and review (to Gilead):

27-29 July 2016

Estimated time of public release (based on CADTH/CDR timeline):

+ 19 to 25 weeks



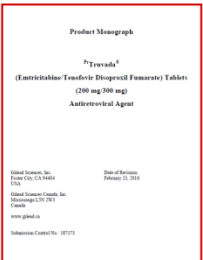


Executive Officer Role: Listing Drugs in Ontario



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Truvada “pathway” for Ontario



Listing Truvada in Ontario?

- Ontario Public Drug Program Executive Officer has a number of options for *listing* Truvada for public cost-coverage
 1. General Formulary
 2. General Formulary (Limited Use)
 3. Exceptional Access Program
 4. Exceptional Access Program (Facilitated Access)
 5. ?????
- Based on the existing categories and procedures under publicly funded drug system in Ontario

Ontario clicks

- **Ontario Public Drug Programs**
<http://www.health.gov.on.ca/en/public/programs/drugs/>
- **How are drugs approved in Ontario**
<http://www.health.gov.on.ca/en/public/programs/drugs/approval/approval.aspx>
- **General Formulary**
http://www.health.gov.on.ca/en/pro/programs/drugs/odbf_mn.aspx
- **Limited Use**
http://www.health.gov.on.ca/en/public/programs/drugs/programs/odb/opdp_limited_use.aspx
- **Exceptional Access Program:**
http://www.health.gov.on.ca/en/public/programs/drugs/programs/odb/opdp_eap.aspx



Listing Truvada in Ontario?

- Ontario Public Drug Program Executive Officer has a number of options for listing Truvada for cost-coverage

1. General Formulary

2. General Formulary

3. Exception

- 4.

- 5.

Each option has **implications for access:**
Who eligible? What Process? What
“costs”?

The Ontario Drug Benefit (ODB)

- ODB covers more than 4,300 prescription drug products

- Covers residents ... who are eligible
 - ▶ social assistance recipients (Ontario Works, ODSP)
 - ▶ seniors
 - ▶ people with high drug costs relative to their income (Trillium Drug Program)
 - ▶ residents of LTC facilities

ODB Formulary Listings

- General Benefit
 - ▶ Listed in the “formulary”
 - ▶ Cost-covered for ODB-eligible recipients, without specific conditions, at pharmacy
 - ▶ Different admin procedures for different people (e.g., drug card, Trillium)
- Limited Use
 - ▶ Reimbursed for ODB recipients only when prescribed according to criteria/conditions outlined for product in formulary
 - ▶ Limited Use drug products demonstrate efficacy, safety, and cost-effectiveness for certain specific indications



Exceptional Access Program

- EAP Facilitated Access
 - ▶ Prescription by physician registered under the Facilitated Access mechanism
 - ▶ Specific lists of drugs that approved physicians can prescribe w/out going through EAP for specific medical conditions
 - ▶ Includes HIV/AIDS



Exceptional Access Program

- Exceptional Access Program (EAP)
 - ▶ Drugs recommended by Ontario CED, placed on EAP by OPDP executive officer
 - Drugs not included on the ODB formulary
 - ▶ Where no listed alternative is available
 - ▶ Today, often functions as a cost-containment mechanism
 - New Hepatitis C drugs covered under EAP



Other public programs in Ontario

- A number of **federal public drug programs** apply to specific groups of eligible people in Ontario
 - ▶ Canadian Forces
 - ▶ Correctional Service Canada (federal **prisoners**)
 - ▶ Interim Federal Health (**refugee claimants**)
 - ▶ Non-Insured Health Benefits (FNIHB—**First Nations and Inuit**)
 - ▶ Veterans Affairs Canada
- Each federal program has its **own drug listing process**.
 - ▶ Currently available under NIHB



Negotiating the Public Drug Plan Price



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Truvada “pathway” for Ontario



Price negotiations & PLAs

- Pan-Canadian Pharmaceutical Alliance (**pCPA**)
 - ▶ Political “block” of public drug plans, negotiates with name-brand pharma for lower prices
- Drug plans and pharma company enter into **Price Listing Agreement for each drug**
 - ▶ May happen after pCPA negotiations or before



Truvada public pricing change?

- A new market for an “old drug”
 - ▶ PrEP is new indication, distinct population, different “medical condition”
 - ▶ Gilead patent on Truvada expires in July 2017
- Gilead has said it **expects to lower price** of Truvada!
 - ▶ **Gilead will participate in new pCPA negotiations**
 - ▶ Then re-negotiation of existing Truvada PLAs with public plans



No drug coverage, no PrEP?



- Gilead **USA** offers patient access programs that provide Truvada for free, or cover the cost of co-payments/deductibles
 - ▶ <http://www.gilead.com/responsibility/us-patient-access/truvada-for-prep-medication-assistance-program>
- Coming to Canada?
 - ▶ We won't know until we ask.
 - ▶ www.truvada.ca coming soon



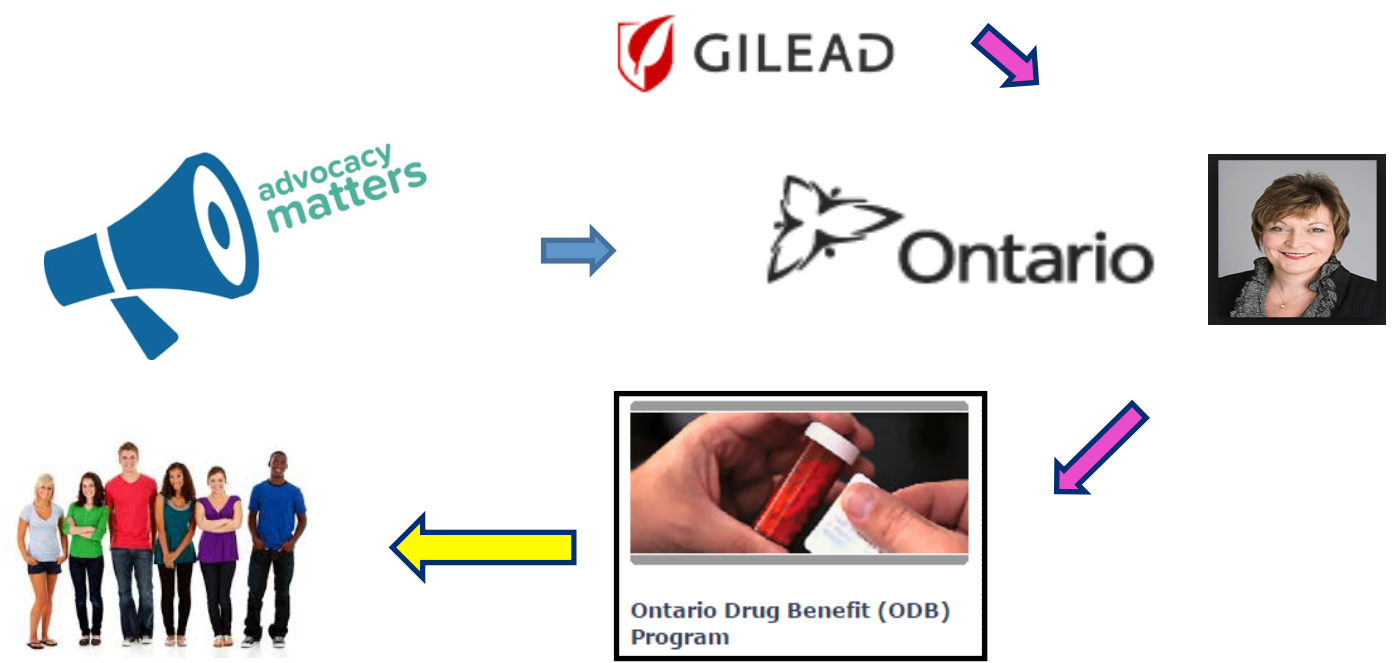


Advocacy for Access



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Truvada “pathway” for Ontario



Patient Group Input



Strengthening treatment, care and support for people living with HIV and HIV/hepatitis C co-infection in Canada

FRANÇAIS

zoom

sound

vision

help

keyword search

SEARCH



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Should Truvada for HIV PrEP be covered under public drug plans?

Participate in CTAC's Patient Group Input Consultation on Truvada for HIV PrEP

Share your experience and perspectives

CTAC wants to hear from one of our two online co

LEARN MORE



Mason At Act shared ACT's photo.

March 15 at 4:43pm

Are you an gay/bi/queer guy who is:
HIV-negative and interested in PrEP but have not taking it?
HIV-positive and have sex with negative guys?

ACT is still looking to fill 2 focus groups on Saturday, March 19. Check out the details below.



NOW RECRUITING
NOW RECRUITING
NOW RECRUITING
NOW RECRUITING
NOW RECRUITING



Maggie's

TORONTO SEX WORKERS ACTION PROJECT



join our mailing list.

contact us at:

e. maggiesinformation@gmail.com

p. 416-964-0150

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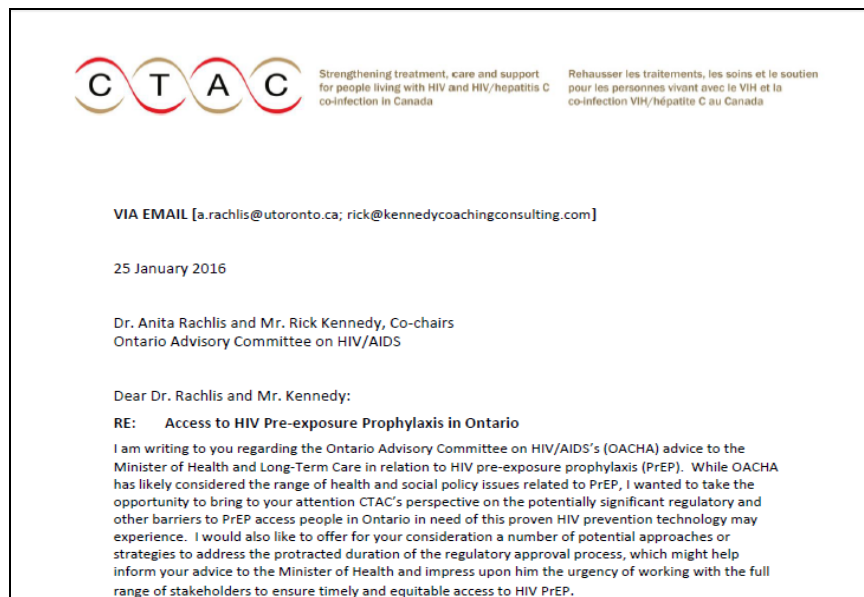
Resources for Workers

Sex Worker Media



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CTAC Letter to OACHA



“CTAC advocates for **equitable, affordable and timely access** to HIV medications, and medications used to treat chronic hepatitis C infection. This includes **medications to prevent HIV, such as Truvada for PrEP**. We wish to raise a number of issues related to PrEP access ... flowing out of these key principles...”

Sent on 26 January 2016... CTAC is awaiting an acknowledgement and/or response.

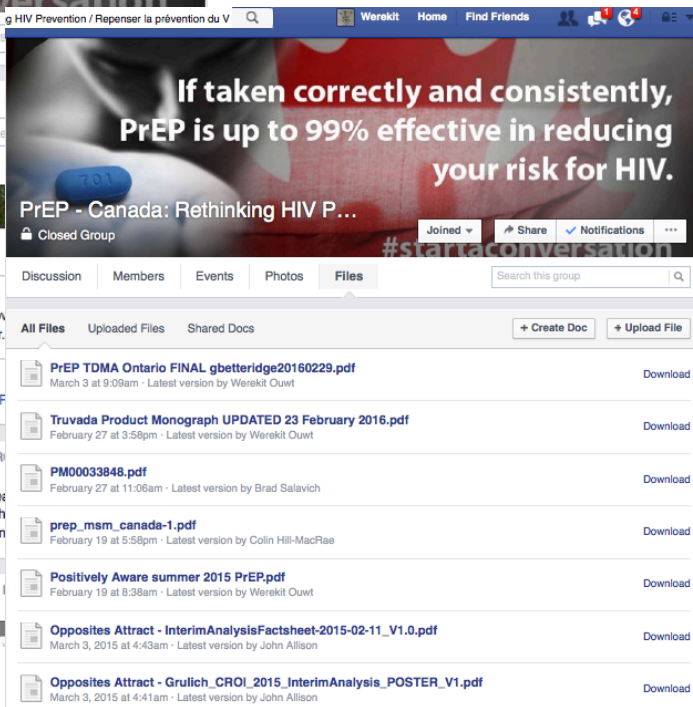


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Communities of interest



Associated with grassroots
**Advocates for PrEP Access in
Canada (APAC)**, website a
work-in-progress
(www.PrEPnow.ca)



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CanPrEP advocates working group

1

Latest activity

Basecamps

Pings

Hey! 10

Campfires

Reports

Find...

Help

CanPrEP

Canadian PrEP Working Group Groupe de travail canadien sur la PrEP

AZ AP BA CA CT CH CT DG DG DG DP DT DT DC GG GD GO HB IC IG ...

Settings

Talk to your team

Your client can't see anything below

Message Board

Glenn B. · Feb 3

Activists united and ignited by urgency for HIV prevention in

Marc-André L. · Feb 1

Citywide campaign transmits love and shows the sexier side

Glenn B. · Jan 29

How a lack of leadership in HIV prevention is failing those

To-dos 4/1

General CanPrEP deve

✓ Send out dial-in informa

proposed agenda for 3 c

Jan 29 Marc-André L.

✓ Send out Doodle poll to

3 committees Jan 15 M

L.

✓ Ask for teleconference s

committee 3 if no one st

14 Marc-André L.

✓ Check-in individually wit

CanPrEP

[← Back to the Clientside](#)

TO THE CLIENT

Ontario Regulatory and Access Strategy Meeting: Doodle Poll

For those of you interested in participating in an Ontario Regulatory and Access strategy meeting, please complete the Doodle Poll (you might have to copy the link and and paste in your browser):

<http://doodle.com/poll/er9mficmp3ep5gi6>

The focus of the meeting will be on organizing, action and advocacy to get Truvada for HIV PrEP cost-covered under Ontario's public drug plan.

Thanks,
Glenn

Glenn Betteridge

Tuesday at 5:06pm



CanPrEP advocates working on..

- Initial in-person meeting in October 2015
 - ▶ Agreement to work together on project-by-project basis; focus on work, NOT building an organization or institution
 - ▶ Adopted Basecamp communication platform in January 2016
 - ▶ Cross Canada representation, community, HCPs, PHAs, local
- Activities in progress (May 2016)
 - PrEP prescriber referral list (local list, possibility of national?)
 - Request for meeting with Gilead to discuss pricing, access, patent expiry and product support for Truvada (by end of May 2016)
 - Regional/provincial support and co-ordination
 - **Ontario** kicking off postcard and sticker campaign to coincide with LGBTQ2S Prides and other summer festivals in Ontario; request for meeting with Ontario Public Drug Program; campaign launch and physician support in Fall 2016
 - **NS** investigating lay of land
 - **Alberta** discussions and organizing involving community and HCPs
 - **BC** community education, awareness, web-site development, social media work, and early stages of communicating with BCCfE, BCCDC, MoHealth, community, PAN



A stylized DNA double helix with the sequence C T A C. The bases are represented by black letters inside the loops of the helix. The helix is colored with red and gold/brown segments.

Pressure points & potential allies for access

- CADTH patient input
- Ontario Minister of Health
- OACHA
- Public Health Ontario
- Medical Officer(s) of Health
- Gilead Canada
- Physician & nurse allies
- Rainbow Health Ontario
- GMSH
- Sherbourne Health Centre
- Ontario HIV Treatment Network



Awareness, Action and Advocacy in Ontario

- What is going on in Ontario, your community, your organization, on-line ... ?



Get social with us!

Joignez-vous à nous!



@CTAC_CAN



/CTAC.CAN



/CTACTALKS



CTAC CANADA



Contact us

Nous joindre

Glenn Betteridge, Policy researcher

glenn@ctac.ca

437-222-2822 x232

Terry Santoni, Program assistant

terry2@ctac.ca

437-222-2822 x231

