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.
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

  - 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 per pill \times 365 \text{ days} / 12 \text{ months} = $991.58 + $12 \text{ dispensing fee} = \$1,003.58)$
The Pathway to Public Listing
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

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

Health Canada review & approval (safety, efficacy & quality) = NOC, PM, clinical indication

Health Technology Assessment (HTA) #1: CADTH/CDR (comparative clinical and cost-effectiveness) = recommendation on public listing

Executive Officer, Ontario Public Drug Programs

Private drug insurance coverage

Price negotiations (pCPA, public drug plans, Gilead) = Price Listing Agreements

• ODSP/OW
• Seniors
• Trillium Drug Plan

Ontario Drug Benefit (ODB)
Formulary GB, Formulary LU, Exceptional Access Program, EAP FA

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Truvada “pathway” for Ontario

GILEAD

Health Canada

Canada.ca

Ontario

Common Drug Review

CADTH

Evidence Driven.

Ontario Drug Benefit (ODB) Program

CTAC

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

2017

- Gilead’s Truvada Patent Expires (July)
Health Canada Review & Approval
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

- 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

Truvada®
(Emtricitabine/Tenofovir Disoproxil Fumarate) Tablets
(200 mg/300 mg)
Antiretroviral Agent

Gilead Sciences, Inc.
Foster City, CA 94404
USA

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

UPDATED 23 February 2016, to include new indication for HIV PrEP
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 / Pharmaco-economic 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
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)
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
CDR allows patient input

28 March 2016

CTAC, ACT and Maggie’s filed patient input submissions

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CDEC recommendation

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

<table>
<thead>
<tr>
<th>Key Milestone</th>
<th>Target Date</th>
<th>Actual Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Application accepted for review</td>
<td>2016-Mar-17</td>
<td>2016-Mar-17</td>
<td>Review has been initiated 2016-Mar-18</td>
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<tr>
<td>Patient group input received</td>
<td>2016-Mar-20</td>
<td>2016-Mar-20</td>
<td>Call for patient input posted on 2016-Feb-04, Patient group input deadline: 2016-Mar-28</td>
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<tr>
<td>Patient group comments on input summary received</td>
<td>2016-Jun-03</td>
<td>2016-Jun-03</td>
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<tr>
<td>CDEC review report sent to applicant</td>
<td>2016-Jul-06</td>
<td>2016-Jul-06</td>
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<tr>
<td>CDEC review team comments on draft CDEC review report(s) sent to applicant</td>
<td>2016-Jul-10</td>
<td>2016-Jul-10</td>
<td></td>
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<tr>
<td>Canadian Drug Expert Committee (CDEC) meeting</td>
<td>2016-Jul-20</td>
<td>2016-Jul-20</td>
<td></td>
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<tr>
<td>CDEC recommendation &amp; related CDEC review report(s) sent to drug plans and applicant</td>
<td>2016-Jul-27 to 2016-Jul-29</td>
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**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
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

- How are drugs approved in Ontario

- General Formulary

- Limited Use

- Exceptional Access Program:
Listing Truvada in Ontario?

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Each option has implications for access:
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 (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
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

- Coming to Canada?
  - We won’t know until we ask.
  - www.truvada.ca coming soon
Advocacy for Access
Truvada “pathway” for Ontario

Gilead

advocacy matters

Ontario

Ontario Drug Benefit (ODB) Program

CTAC

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Patient Group Input

CTAC

Striving treatment, care and support for people living with HIV/AIDS in Canada.

Keyword search

SEARCH

Mason At Act shared ACT's photo.
March 15 at 4:43pm

Are you an gay/bisexual 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.

Maggie's
TORONTO SEX WORKERS ACTION PROJECT

contact us at:
e. maggiesinformation@gmail.com
p. 416-964-0150

Home About Get Involved Press Releases Resources for Workers Sex Worker Media
“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.
Communities of interest

CanPrEP advocates working group

CanPrEP
Canadian PrEP Working Group
Groupe de travail canadien sur la PrEP

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 paste it in your browser):

http://doodle.com/poll/er9mfcmp3ep5gi6

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
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
Toronto activity
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

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