

# Pre-exposure Prophylaxis for HIV

## Eligibility Criteria and Clinical Guidance for Manitoba HIV Pre-Exposure Prophylaxis

MANITOBA HEALTH, SENIORS AND LONG-TERM CARE | Public Health Branch  
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## **Introduction and Background**

**HIV pre-exposure prophylaxis (PrEP)**, when taken daily, is a highly effective pharmacologic means of preventing HIV infection in individuals who test negative for HIV and are at ongoing high risk of acquiring the infection.

**PrEP should be used as part of a comprehensive programmatic HIV prevention strategy involving the care and treatment of HIV-infected individuals (“treatment as prevention”) and risk-reduction strategies to minimize the risk of HIV acquisition, with the goal of reducing or eliminating new HIV infections in HIV-negative persons.**

In Fall 2021, PrEP was added to the provincial drug program formularies. The effective date and specific provincial eligibility criteria for coverage are in a Manitoba Drug Benefits and Interchangeability Formulary Bulletin here: <https://www.gov.mb.ca/health/mdbif/bulletins.html>.

## **Drug Regimen for PrEP**

PrEP is typically prescribed as daily continuous prophylaxis. Efficacy is highly dependent on adherence to the regimen. PrEP prevents HIV infection by preventing replication of the virus. PrEP should be taken daily as prescribed to generate sufficient levels of the drug within the blood and tissues to stop multiplication of the virus and establishment of infection.

Medication for use as PrEP is daily generic fixed drug combination FTC/TDF (Emtricitabine 200mg + Tenofovir disoproxil fumarate 300mg) taken orally by persons at high and ongoing risk for HIV infection who meet the provincial eligibility criteria.

*Note: ‘On-demand HIV PrEP’ is not recommended or covered under provincial drug programs (Pharmacare and Employment and Income Assistance).*

## **PrEP Eligibility Criteria**

(Adapted from 2017 Canadian guidelines, Tan et al. 2017 and Alberta PrEP guidelines October 2020)

Access to PrEP is based on specific eligibility criteria to identify individuals at high and ongoing risk of acquiring HIV infection, and therefore most likely to benefit from the intervention. A detailed assessment of risks and benefits should be completed by a health care provider prior to starting PrEP as well as ongoing assessments including HIV status, sexually transmitted and blood borne infections (STBBIs) screening, and monitoring for medication side effects.

**Individuals who are HIV-negative, and meet the following clinical criteria are eligible for HIV PrEP with generic fixed drug combination FTC/TDF:**

### **1. Men Who Have Sex with Men, Trans Women and Gender Diverse People**

- Condomless anal sex within the last six months **and any of**:
  - Infectious syphilis or bacterial STI (gonorrhea or chlamydia) in the past 12 months
  - nPEP (non-occupational HIV post-exposure prophylaxis) more than once
  - Ongoing sexual relationship with HIV-positive partner(s) with substantial risk of transmissible HIV (e.g., viral load >40 copies/mL\*) or HIV status unknown but from a higher risk population (e.g., men who have sex with men (MSM), persons who inject drugs (PWID))
  - HIRI-MSM risk score  $\geq 11$  (HIV Infection Risk Index for MSM; see Appendix A: HIRI-MSM risk assessment tool)
- Gender diverse people are included in the eligibility criteria as incorrect assumptions can be made about the sexual practices of individuals.
- Not indicated for those in a monogamous relationship with a single partner with no or negligible risk of having transmissible HIV (e.g., HIV negative, HIV positive but virus suppressed with viral load  $\leq 40$  copies/mL\*, or HIV status unknown but risk profile similar to the general population (Tan et al. 2017)).

### **2. Heterosexual People**

- Recommended for the HIV-negative person with ongoing exposure to HIV-positive partner(s) involving condomless vaginal or anal sex, where the HIV-positive partner(s) has a substantial risk of having transmissible HIV (i.e., not on or not adherent to antiretroviral treatment)
- Consider PrEP for the HIV-negative person in similar situations where the HIV-positive partner(s) has a lower, but non-negligible risk of transmissible HIV:
  - viral load detectable (>40 copies/mL\*) or
  - viral load usually undetectable\* but concomitant STI present at time of exposure (recognizing that undetectable viral load gives a very low likelihood of transmission, but the presence of an STI may increase the presence of virus in ulcers (Boily MC et al. 2009) or at mucosal surfaces), or
  - HIV status unknown, but from a high-prevalence population – MSM, PWID, countries with high HIV prevalence (see UNAIDS AIDS info at <https://aidsinfo.unaids.org/>)
- Not indicated for those in a monogamous relationship with a single partner with no or negligible risk of having transmissible HIV (e.g., HIV negative, HIV positive but virus suppressed with viral load  $\leq 40$  copies/mL\*, or HIV status unknown but risk profile similar to the general population (Tan et al. 2017)).

### 3. People Who Inject Drugs

- PrEP may be considered when there is ongoing or anticipation of ongoing sharing of injection drug use paraphernalia (needles, syringes, spoons, foil, cotton filters, etc.) with a person with a non-negligible risk of HIV infection:
  - Detectable viral load\* or
  - HIV status unknown but from a high-prevalence population – MSM, PWID, countries with a high HIV prevalence

\*For the purposes of this document, an undetectable viral load is defined by two sequential measurements of HIV viral load  $\leq 40$  copies/ml as the result on at least two occasions separated in time by four to six months.

### **Prescribing PrEP and Ongoing Care**

PrEP should be prescribed in the context of clinical settings experienced in the delivery of sexual health services by a prescriber experienced in the treatment and prevention of STBBIs.<sup>1</sup>

Prescribers must be licensed Manitoba-eligible prescribers, knowledgeable about the management of STBBIs and of PrEP, and responsible for the ongoing care of these clients.

Prescribers must ensure that clients meet the provincial eligibility criteria established in the Manitoba Drug Benefits and Interchangeability Formulary Bulletin found here: <https://www.gov.mb.ca/health/mdbif/bulletins.html>, and provide baseline and follow-up clinical care as described by The Manitoba HIV Program HIV Prevention Guidelines. Follow-up clinical and laboratory evaluation are critical and recommended after 30 days, every three months thereafter, and after PrEP is discontinued.

The Manitoba HIV Program HIV Prevention Guidelines provides clinical guidance for PrEP including initiation, risk categories, monitoring, risks and benefits, special populations (e.g., clients with hepatitis B infection, pregnant or breastfeeding), PrEP cessation as well as other HIV prevention strategies. Find these guidelines at <https://mbhiv.ca/guidelines>.

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<sup>1</sup> CADTH Canadian Drug Expert Committee Final Recommendation (2016). EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE. Indication: Pre-exposure Prophylaxis of HIV-1 Infection. [https://www.cadth.ca/sites/default/files/cdr/complete/SR0479\\_complete\\_Truvada\\_Aug-26-16.pdf](https://www.cadth.ca/sites/default/files/cdr/complete/SR0479_complete_Truvada_Aug-26-16.pdf)

The following resources for PrEP guidelines in Canada have further guidance for health care providers:

Alberta PrEP Information for Health Professionals, including guidelines and provider training module:

<https://www.albertahealthservices.ca/info/Page16048.aspx>

Canadian Guideline on HIV Pre-Exposure Prophylaxis and Nonoccupational Postexposure Prophylaxis:

<https://www.catie.ca/canadian-guideline-on-hiv-pre-exposure-prophylaxis-and-nonoccupational-postexposure-prophylaxis>

<https://www.cmaj.ca/content/189/47/E1448>

BC PrEP Information for Health Professionals:

<http://bccfe.ca/hiv-pre-exposure-prophylaxis-prep>

## **Appendix A: HIRI-MSM risk assessment tool**

Adapted from Canadian Guidelines on HIV PrEP and nPEP, version 2.1, November 13, 2017.

This tool has not been validated in Manitoba and its performance characteristics are unknown in our population.

<b>Question Number</b>	<b>Question</b>	<b>Response</b>	<b>Score</b>
1	How old are you today? (years)	< 18 years 18-28 years 29-40 years 41-48 years ≥ 49 years	0 8 5 2 0
2	How many men have you had sex with in the last 6 months?	> 10 men 6-10 men 0-5 men	7 4 0
3	How many of your male sex partners were HIV positive?	> 1 positive partner 1 positive partner < 1 positive partner	8 4 0
4	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	≥ 1 times 0 times	10 0
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times 0-4 times	6 0
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes No	5 0
7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes No	3 0
<b>Total Score:</b> (Add the scores in the right-hand column.)			

Adapted from Alberta PrEP Guidelines and Canadian Guidelines on HIV PrEP and nPEP