

PrEP Provider FAQs

PrEP

PrEP+talk

What is PrEP?

PrEP is Pre-Exposure Prophylaxis for HIV. It is the use of antiretroviral medication to prevent HIV infection. PrEP can be used by HIV-uninfected individuals who are at risk of HIV infection either through sexual exposure or injection drug use. PrEP has been approved by Health Canada; the drugs used for PrEP are tenofovir disoproxil fumarate and emtricitabine (TDF/FTC), or tenofovir alafenamide and emtricitabine (TAF/FTC). Both options are available combined in a single tablet. Generic formulations of TDF/FTC are available in Canada and have commonly been used in the treatment and prevention of HIV infection.

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What are the guidelines for prescribing PrEP?

Canadian guidelines for prescribing PrEP and PEP were published in 2017 and updated in 2018. The guidelines can be found here: <https://www.cmaj.ca/content/cmaj/189/47/E1448.full.pdf>

For more information on guidelines and prescribing PrEP, visit <https://ontarioprep.ca/>

Who should be offered PrEP?

PrEP should be offered to:

Men (including trans men) who have sex with men OR trans women who have sex with men who meet the following criteria:	Heterosexual women and men who meet the following criteria:	Anyone, regardless of gender, who meet the following criteria:
<ul style="list-style-type: none">• An HIV positive partner who is not undetectable• Recent bacterial STI (GC, CT) or syphilis• Multiple sexual partners• History of inconsistent or no condom use• Use of methamphetamine in past 6 months	<ul style="list-style-type: none">• An HIV positive partner who is not undetectable• History of inconsistent or no condom use or past syphilis diagnosis, if patient is in a high prevalence area or network	<ul style="list-style-type: none">• Injects drugs and sometimes shares needles• Has used PEP for non-occupational sexual exposures or has had multiple courses of PEP

For more information on risk stratification visit <https://ontarioprep.ca/risk-stratification>

Who can prescribe PrEP?

Any licensed health care provider can prescribe PrEP. TDF/FTC is listed on ODB as a general benefit and does not require any special access. Specialization in infectious diseases or HIV medicine is not required. Any primary care provider with patients who are at high risk of HIV should consider offering and prescribing PrEP.

How is TDF/FTC prescribed?

Most often PrEP is taken daily by mouth. Intermittent dosing strategies have also been studied. The Canadian guidelines provide information on the prescription and follow-up needed.

PrEP should be discontinued immediately if the patient either becomes HIV infected or experiences toxicities or symptoms that cannot be managed.

How important is adherence to PrEP?

Adherence is critical. In all PrEP clinical trials to date, PrEP efficacy appeared to depend on adherence. According to a dedicated analysis of adherence in those trials, PrEP was non-efficacious when adherence was low, but when moderate or high adherence was achieved, efficacy was modest or relatively high, respectively. Among the study subjects with detectable plasma tenofovir levels in iPrEx, Partners PrEP, TDF2 and BTS, efficacy ranged from 74 to 92%. Adherence to PrEP was also found to be highly associated with reduction of HIV risk in an open-label study (iPrEX OLE). Among participants with drug detected by dried blood spot, HIV incidence ranged from 4.7 infections per 100 person-years (no drug detected) to 0.6 per 100 person-years (two to three tablets per week). There were no HIV infections in participants using four or more tablets per week.

How quickly does PrEP provide protection?

Data from pharmacokinetic studies suggest that individuals need to take PrEP for:

- At least 7 days to achieve protective levels in rectal tissue and plasma
- At least 21 days to achieve protective levels in cervicovaginal tissue

Is PrEP safe?

PrEP is considered safe and well-tolerated. Although TDF/FTC has caused renal toxicity and decreased bone mineral density when used for HIV treatment and administered for months and years, in PrEP studies to date, it has not caused serious safety concerns. Preliminary data suggest that TAF/FTC has less impact on the kidney and bone density and clinical studies are ongoing.

TDF/FTC is considered safe for all populations, including women of childbearing age (it is considered in Pregnancy Class B). TDF/FTC is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high (such as in a serodifferent or serodiscordant partnership) and because pregnancy itself is associated with an increased risk of HIV acquisition. TAF/FTC has been approved for use in adults weighing at least 77 lb (35 kg), excluding cisgender women or people who inject drugs.

Who is not eligible for PrEP?

- **Anyone who is already HIV positive should not be on PrEP.** It is important to exclude individuals who have acute HIV infection. All patients initiated on PrEP should have testing one month after starting to ensure they were not in the window period for detecting HIV infection.
- **Anyone with renal insufficiency with an eGFR < 60 ml/min.** Ensure that the patient's calculated creatinine clearance is ≥ 60 mL/minute before initiating PrEP.
- Those who indicate that they are not ready to adhere to daily oral medication should not be prescribed PrEP (since, as described above, efficacy is extremely limited when patients do not adhere to the dosing schedule).

Does PrEP work in women?

Current clinical guidelines include women as appropriate candidates for TDF/FTC as PrEP. As with all PrEP patients, adherence is critical. Two trials of PrEP in women were stopped early for futility by their respective data safety and monitoring boards. Low adherence among the participants was thought to be a substantial factor in the futility finding. Other studies that included both men and women (TDF-2, Partners PrEP) in which higher levels of adherence were achieved did show efficacy among women. Recent data suggest that women may need higher levels of adherence than men to achieve protective levels of drug in the female genital tract.

Can adolescents take PrEP?

The Canadian PrEP guidelines do not have any statement on adolescents. Based on the experience of using PrEP for HIV treatment and PEP among adolescents, the CDC and the International Antiviral Society-USA recommend the use of TDF/FTC or TAF/FTC as PrEP for adolescents at high sexual or other behavioral risk for HIV infection. TDF/FTC is the only approved formulation for cisgender women or other people at risk of HIV acquisition through receptive vaginal sex.

As with every patient, but especially with younger adolescents:

- Carefully weigh the potential benefits and risks, including acquiring HIV infection.
- Refer to the institution's policy or consult with the institution's legal department about consent to care for adolescents under 18 years of age according to Ontario law.
- Make clear that the efficacy of PrEP is highly dependent on strict adherence.

What baseline assessment is required before initiating PrEP?

The two most critical tests are for HIV and renal function (creatinine/eGFR).

HIV testing should be conducted immediately prior to starting PrEP. The Canadian guidelines recommend that baseline testing be conducted with a lab-based fourth-generation HIV test (the blood test done through Public Health Ontario uses fourth-generation screening technology).

If acute HIV infection is suspected, additional laboratory evaluation with an HIV RNA nucleic acid amplification test (if available) or repeat fourth-generation assay 7 to 21 days later is suggested, and PrEP should be deferred or suspended until results are received.

All patients should have a serum creatinine performed at baseline to ensure that their eGFR is >60ml/min.

For further information on baseline screening, see the Canadian prep guidelines at <https://www.cmaj.ca/content/cmaj/189/47/E1448.full.pdf> or the OHTN website <https://ontarioprep.ca/screening>



What additional support and ongoing assessment are required for patients on PrEP?

PrEP should be prescribed as part of a strategy for HIV prevention. This includes adherence assessment, risk reduction counselling and condoms.

Monitoring	Frequency
Prevention and medication support	
Assess adherence	Every visit
Provide risk reduction counseling	
Offer condoms	
Manage side effects	
Laboratory testing	
HIV testing	Every three months
Screening for GC/CT	
Syphilis serology	
Creatinine	
Pregnancy testing (as appropriate)	

Will PrEP be covered for my patients?

Many insurance plans cover PrEP. For private drug coverage, patients rarely have issues. For youth 24 years old and younger without a private drug plan, OHIP+ fully covers the cost of TDF/FTC as does the Seniors Coverage for those over the age of 65. The Ontario Drug Benefit, Ontario Works and the Ontario Disability Support Program also fully cover the cost of TDF/FTC as PrEP. Those without coverage can apply to the Ontario Trillium Drug Program to help cover the costs with a co-pay based on income. For more information about the Trillium Drug Program visit <https://www.ontario.ca/page/ontario-trillium-benefit>. Often pharmacies will help patients apply for Trillium.

For those who are covered by the federal government through either Interim Federal Health or Non-Insured Health Benefits, PrEP is covered by those plans.

Additionally, the PrEPStart provides three months of free PrEP for people at risk of HIV who do not currently have drug coverage. This program lets them start PrEP right away and gives them three months to arrange drug coverage so they can stay on PrEP as long as needed. Details about PrEPStart and access to the prescription form can be found here: <https://ontarioprep.ca/prepstart/>

For more information about how to pay for PrEP, including coverage options for those without OHIP, please visit: <https://ontarioprep.ca/for-health-care-providers/pay/>

Should PrEP be used for serodiscordant couples (one HIV positive, the other HIV negative)?

If an individual is in a serodiscordant relationship and is monogamous with their HIV positive partner, as long as the partner maintains an undetectable viral load, PrEP provides no added benefit in terms of HIV prevention. In cases where the HIV negative person has other sexual partners of unknown HIV status then PrEP should be considered.

For more information about PrEP visit <https://www.ontarioprep.ca>

