

# Victorian guidance on pre-exposure prophylaxis (PrEP)

Updated April 2018

## **Acknowledgement**

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# 1. Purpose

This document provides medical practitioners with information on pre-exposure prophylaxis (PrEP) for the prevention of human immunodeficiency virus (HIV) transmission. This includes clinical guidelines for prescribing PrEP, eligibility criteria, monitoring and ongoing care, and evidence for PrEP and other biomedical prevention strategies

The Department of Health and Human Services recommends that medical practitioners who prescribe PrEP use this guidance document in conjunction with the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) *HIV pre-exposure prophylaxis: clinical guidelines*;<sup>1</sup> and the Sexually Transmissible Infections in Gay Men Action Group's (STIGMA) *Australian Sexually Transmitted Infection and HIV Testing Guidelines*<sup>2</sup> to ensure a high standard of sexual health care when prescribing PrEP.

## 2. Background

The Victorian Government has set the ambitious goal of virtually eliminating new HIV transmissions in Victoria by 2020. The *Victorian HIV Strategy 2017-2020* outlines priority actions for achieving this goal, as well as the 95-95-95 targets by 2030: 95 per cent of people living with HIV will be diagnosed; 95 per cent of those diagnosed will be on effective treatments; and 95 per cent of people on treatment will have an undetectable viral load.<sup>3</sup>

The Victorian Government considers PrEP to be one of several vital tools in achieving these goals. Along with undetectable viral load, post-exposure prophylaxis (PEP), and condoms, easy and affordable access to PrEP can help individuals take charge of their sexual health and wellbeing.

### Pre-exposure prophylaxis (PrEP)

PrEP is the use of HIV anti-viral medications to prevent the transmission of HIV. When taken daily, PrEP is up to 99 per cent effective in preventing HIV.<sup>4</sup> Currently only one medication is approved for use as PrEP: co-formulated tenofovir and emtricitabine. It has been used for many years to treat HIV under its brand name, Truvada.

PrEP is one of many tools used to reduce the risk of HIV transmission, in addition to condoms and undetectable viral load (UVL is when a person with HIV has a viral load of less than 200 copies/mL and there is no risk of transmission). PrEP does not prevent other sexually transmissible infections.

### Clinical evidence on PrEP

In 2012, the World Health Organization (WHO) released preliminary guidance on PrEP. The WHO guidance was based on evidence from multiple clinical trials demonstrating the effectiveness of two key ARVs, tenofovir disoproxil fumarate (TDF), and emtricitabine (FTC), in preventing the transmission of HIV infection in HIV-negative adults.<sup>5</sup>

In a number of countries, these ARVs are sold as an oral fixed-dose combination under the brand name Truvada® (Truvada).<sup>6</sup>

In 2012, the United States Food and Drug Administration approved the use of Truvada for PrEP. The United States Centers for Disease Control (CDC) released clinical practice guidelines for men who have sex with men and heterosexuals in 2015, which were updated to include people who inject drugs.<sup>7</sup>

Since the development of the 2012 WHO guidance, continuing trials have added to the evidence base that PrEP, when taken every day, has the potential to reduce the risk of HIV infection by more than 99 per cent.<sup>4</sup> For heterosexual women or transgender men having vaginal sex, PrEP must be taken every day in order to be effective.<sup>8</sup>

In September 2015, WHO recommended that oral PrEP containing tenofovir should be offered as an additional prevention choice for people at substantial risk of HIV infection.<sup>9</sup>

## PrEP in Australia

Several Truvada-based PrEP demonstration projects have been operating in Victoria, South Australia, Western Australia, Tasmania, ACT, Queensland, and New South Wales. When these demonstration projects began, Truvada was approved by the Therapeutic Goods Administration (TGA) only for the treatment and management of HIV infection.

In February 2015, the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) released clinical practice guidelines for S100 prescribers on prescribing PrEP, based on guidelines from the United States Centers for Disease Control.<sup>7</sup> The ASHM guidelines were updated in 2017.<sup>1</sup> The ASHM guidelines make reference to:

- research evidence about PrEP effectiveness and safety
- PrEP in the Australian context
- links to clinical guidance
- a guide to accessing Truvada for PrEP in Australia
- behavioural risk assessment and eligibility criteria for PrEP
- patient monitoring and management.

In May 2016, the TGA approved Truvada for use as PrEP. However, as PrEP was not available on the Pharmaceutical Benefits Scheme (PBS), cost was a significant barrier to access. As a more affordable alternative, many consumers utilised the TGA's Personal Importation Scheme,<sup>10</sup> purchasing PrEP from overseas through the internet with an Australian prescription from their doctors, or participated in one of the clinical trials offered by states and territories.

In February 2018, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended PBS listing for brand-name Truvada and two generic formulations, produced by Mylan Alphapharm and Generic Health/Lupin Pharmaceuticals, respectively. PrEP became available on the PBS on 1 April 2018 for all individuals at medium to high risk of HIV.

## Undetectable viral load (UVL) and treatment as prevention (TasP)

Viral load is a key factor in the transmission of HIV. Antiretroviral medications (ARVs) used in the treatment and management of HIV infection inhibit the replication of HIV. Adherence to antiretroviral treatment (ART) can lower and suppress HIV viral load to undetectable levels, reducing the risk of HIV transmission to almost zero.<sup>11</sup>

The use of ART in HIV-positive people to reduce the risk of onwards HIV transmission, is often referred to as *treatment as prevention* or TasP. When people living with HIV are on effective treatments they can achieve an undetectable viral load, meaning the amount of virus in their body is extremely low. Evidence indicates that when a person is undetectable, they are uninfected, and cannot transmit the virus.<sup>12, 13, 14</sup>

To promote this fact, the Victorian Government has endorsed the U=U campaign, short for *undetectable equals untransmittable*. More information on U=U can be found at <https://www.preventionaccess.org>.

## Post-exposure prophylaxis (PEP)

Post-exposure prophylaxis (PEP) is the use of one or more antiretroviral drugs to reduce the risk of transmission of HIV, following a known or possible exposure to HIV. Patients who have had a recent HIV exposure (within 72 hours) are normally assessed for non-occupational post-exposure prophylaxis (NPEP).<sup>15</sup>

For patients who repeatedly present for PEP, PrEP is recommended. More information is available from the Victorian NPEP Service by phoning 1800 889 887 (NPEP Hotline) or via the web page (<http://www.alfredhealth.org.au/services/hp/victorian-npep-service/>).

## 3. Accessing PrEP in Victoria

In recognition of clinical evidence on the efficacy of PrEP, the Victorian Government, in conjunction with Alfred Health and the Victorian AIDS Council, established a public health research study known as PrEPX. PrEPX sought to decrease new transmissions of HIV by expanding access to PrEP for Victorians at high risk of HIV. The study commenced in July 2016, and ended on 31 March 2018. With PrEP available on the PBS from 1 April 2018, people who hold a Medicare card are able to access their PrEP care and medications from their usual general practitioner and community pharmacy.

### Access for people ineligible for Medicare

People who are ineligible for Medicare can access PrEP by requesting a prescription issued from an Australian medical practitioner, then ordering a three month supply of generic TDF/FTC over the internet, and importing these antiretrovirals under the TGA Personal Importation Scheme<sup>16</sup> Some pharmaceutical companies may also offer compassionate access schemes for people unable to access PrEP through Medicare.

Under the Personal Importation Scheme, the patient is the 'personal importer' and they accept that the quality, safety, and efficacy of the generic formulation may be unknown, and are prepared to accept any risks associated with taking the medication. With a number of different websites selling pharmaceuticals online, regulation and checks on the type of prescription sent, or re-use of prescriptions, is varied and beyond the control of the issuing medical practitioner.

Several community groups offer guidance and support to people who want to import PrEP from overseas: PrEPaccessNOW (PAN), and PrEP'd for Change They have developed resources for practitioners and patients to help them understand the prescription and importation process.

For more information on the personal importation of PrEP, visit: [www.pan.org.au/get-prep/](http://www.pan.org.au/get-prep/) or [www.prepforchange.com](http://www.prepforchange.com).

## 4. Prescribing PrEP

ASHM has produced the *2017 Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines*. The ASHM guidelines outline behavioural risk and eligibility criteria for men who have sex with men (MSM); heterosexual men and women; trans and gender diverse people; and people who inject drugs (PWID).

PrEP is recommended for all individuals at high risk of HIV. The ASHM clinical guidelines recommend the prescribers take a case-by-case approach in prescribing PrEP, as it may still be indicated in people who fall outside the recommended eligibility criteria. In these situations, clinicians with limited experience in sexual health or management of PrEP are encouraged to contact experienced clinicians for further guidance. These guidelines can be downloaded at [http://viruseradication.com/journal-details/Australasian\\_Society\\_for\\_HIV,\\_Viral\\_Hepatitis\\_and\\_Sexual\\_Health\\_Medicine\\_HIV\\_pre-exposure\\_prophylaxis:\\_clinical\\_guidelines/](http://viruseradication.com/journal-details/Australasian_Society_for_HIV,_Viral_Hepatitis_and_Sexual_Health_Medicine_HIV_pre-exposure_prophylaxis:_clinical_guidelines/).

For support or further information visit the Alfred Health statewide HIV service at: <http://www.alfredhealth.org.au/services/statewide-services/victorian-hiv-service>

## 5. Monitoring sexual health

In Australia, gay and bisexual men (GBM) and men who have sex with men (MSM) are disproportionately affected by sexually transmissible infections (STI). This is attributed, in part, to changes in sexual behaviour including a decade-long trend increase in condomless anal intercourse with casual partners. As many STI are asymptomatic, regular and frequent STI testing is important to detect infections that may otherwise remain undiagnosed and untreated.

The Department of Health and Human Services recommends that medical practitioners who prescribe PrEP use this guidance document in conjunction with the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) *HIV pre-exposure prophylaxis: clinical guidelines*;<sup>1</sup> and the Sexually Transmissible Infections in Gay Men Action Group's (STIGMA) *Australian Sexually Transmitted Infection and HIV Testing Guidelines*<sup>2</sup> to ensure a high standard of sexual health care when prescribing PrEP.

## 6. Guiding principles for prescribing PrEP

For medical practitioners prescribing PrEP to an HIV-negative patient, there are core guiding principles for developing a patient management plan:<sup>7</sup>

- conduct baseline HIV testing and ongoing, three-monthly HIV testing to ensure the patient remains HIV-negative – consider using a recall system to encourage regular testing
- ensure the patient understands that PrEP must be taken on a daily basis and support the patient with adherence strategies
- ensure that any patient who has receptive anal sex and/or insertive penile sex understands that they need to have taken seven daily doses of PrEP before it is effective
- women who have receptive vaginal sex and transgender men who have front hole sex understand that they also need to have taken seven daily doses of PrEP before it is effective
- ensure the patient understands that they should continue PrEP for at least 28 days after their last risk exposure if they wish to stop PrEP
- ensure the patient understands that condoms should be used to prevent STI and provide advice, if required, about making condoms more useable for them, and that condoms should be used to prevent HIV infection if the patient misses doses of PrEP
- routinely (every three months) screen the patient for STI, particularly syphilis, gonorrhoea and chlamydia
- routinely (every six months) test the patient's kidney function
- ensure the patient understands a maximum of a three-month supply can be provided on one prescription, and it is the patient's responsibility to ensure that timely appointments are made so that adherence is not interrupted
- provide new information/evidence on PrEP to the patient in a timely manner.

## 7. Recommended appointment schedule

The decision to prescribe PrEP may occur over one or more appointments, with the patient understanding that ongoing monitoring is part of the patient-prescriber agreement to prescribe PrEP. An appointment schedule and key recommendations for each appointment are outlined in the table on the following page.



**Table 1: Appointment schedule and key clinical recommendations**

Clinical action	Initial appointment and additional appointments (if required)	One month follow-up	Three months follow-up	Every three months follow-up appointment
PrEP information and discussion which includes: <ul style="list-style-type: none"> <li>information on PrEP and conception/ pregnancy</li> <li>short and long-term side effects</li> <li>adherence</li> <li>risk of developing resistance if HIV is acquired</li> </ul>	✓			
Behavioural risk assessment	✓		✓	✓
HIV Ab/Ag combo test	✓		✓	✓
Assessment of acute HIV infection (< 1 month)	✓	✓	✓	✓
Full STI screen	✓	✓	✓	✓
Hepatitis B test	✓			
Hepatitis C test	✓ (then 1 x year at minimum)			
Serum creatinine test	✓ (then 1 x 6 months)			✓
Communication of test results	✓	✓	✓	✓
Laboratory screening to determine contra-indications for TDF/FTC	✓			
Assessment of TDF/FTC interaction with existing medications/supplements	✓			
Assessment of side effects		✓	✓	✓
60 day PrEP prescription	✓			
90 day PrEP prescription		✓	✓	✓
Adherence counselling/ discussion	✓ ✓	✓	✓	✓

## 8. Prescribing information

For further information, medical practitioners should refer to:

- TGA product information documents/Australian Register of Therapeutic Goods summary
- *Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines (2017 updated guidelines)*<sup>1</sup>
- United States Centers for Disease Control *Pre-Exposure Prophylaxis for the infection of HIV infection in the United States – 2014: Clinical Providers' Supplement*<sup>7</sup>
- World Health Organisation *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV, 2015*<sup>17</sup>
- Gilead Sciences Truvada PrEP Resources<sup>18</sup>

## 9. Supporting documentation for the prescriber and patient

It is recommended that prescribers use supporting documentation with their patient. This may include:

- a prescriber-patient checklist and agreement form for initiating PrEP\* (see Appendix 1)
- *Important Safety Information About TRUVADA to Reduce the Risk of Getting Human Immunodeficiency Virus-1 (HIV-1) Infection*<sup>17\*\*</sup>
- drug information on tenofovir/emtricitabine (TDF/FTC)<sup>6</sup>
- Community and peer support for PrEP users, through PAN ([www.pan.org.au](http://www.pan.org.au)) and PrEP'd for Change ([www.prepdforchange.com](http://www.prepdforchange.com)). These groups also provide guidance for people who are importing PrEP from overseas.

*(\*This template was adapted by the Prahran Market Clinic, Melbourne from a checklist in the United States Centers for Disease Control, Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Providers' Supplement.)*

*(\*\*Prescribers should note that these resources are based on prescribing PrEP in the United States, and not in Australia.)*

## 10. If a patient tests positive for HIV while on PrEP

Advice on management of a patient who seroconverts to HIV while taking PrEP is evolving. Most people on PrEP who acquire HIV infection have not been taking their PrEP regularly, or at all.

If a patient has a positive HIV fourth generation Ab/Ag test while on PrEP:

- a confirmatory HIV test must be conducted
- an HIV genotype test must be conducted
- the patient should be offered antiretroviral therapy without ceasing PrEP, in consultation with an HIV specialist
- the patient must be linked into HIV care as soon as possible, if the prescriber is not an HIV specialist.

It is important not to speculate with your patient as to why seroconversion has occurred, or why PrEP appears not to have worked in the particular circumstances. It is recommended that health care workers who are unfamiliar with HIV care contact Alfred Health for further information and advice.

Alfred Health offers information, assistance, advice, and referrals through the Victorian HIV Service, or the HIV GP Connect line.

GP Connect is a telephone services that provides GPs and other health care workers with assistance and advice on how to deliver an HIV-positive result to a patient, contact details for HIV service providers, and assistance in linking your patient into specialist care. The GP Connect line is available from Monday through Friday from 8 AM to 4 PM, at **0418 459 168**.

Information about the statewide Victorian HIV Service is available from Alfred Health via the web page – <http://www.alfredhealth.org.au/services/statewide-services/victorian-hiv-service>.

Living Positive Victoria is a community organisation that provides support to people living with HIV in Victoria. It runs the Phoenix peer support workshops for people newly diagnosed with HIV, which are tailored to suit people of sexual and gender identities. Living Positive Victoria can also provide the service of a peer navigator, a person living with HIV who can offer one-on-one assistance to link a person newly-diagnosed with HIV to the care, treatment, and support they need. More information is available at <http://www.livingpositivevictoria.org.au>, or on (03) 9863 8734.

# Appendix 1: Guidance on prescribing PrEP

The following tables should only be used as a guide for prescribing PrEP. The inclusion criteria described below should be balanced with the following exclusion criteria – confirmed HIV infection; symptoms consistent with acute HIV infection; underlying renal disease; underlying bone disease; unwillingness to adhere to PrEP regimen or unwillingness to attend follow-up visits<sup>18</sup>.

**There may be a cohort of clients who do not meet either the inclusion or exclusion criteria. In these cases, practitioners should make a clinical judgment in regard to prescribing PrEP based on a client's individual needs and concerns.**

Tables below have been drawn from the *2017 Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines*.<sup>1</sup>

## Behavioural eligibility criteria for PrEP for MSM

A. High risk – recommend prescribing daily PrEP
<p><b>If the client acknowledges having had any of the following in the last 3 months:</b></p> <ul style="list-style-type: none"><li>• At least one episode of condomless anal intercourse (CLAI) with a regular HIV+ partner (not on treatment and/or detectable viral load)</li><li>• At least <b>one</b> episode of receptive CLAI with any casual HIV+ male partner or a male partner of unknown status</li><li>• Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis (during the last 3 months or at screening for PrEP)</li><li>• Methamphetamine use, which may increase the risk of HIV acquisition )</li></ul> <p><b>And:</b></p> <ul style="list-style-type: none"><li>• Being likely to have multiple episodes of CLAI, with or without sharing intravenous drug equipment, in the next 3 months (indicating sustained risk)</li></ul>
B. Medium risk – consider prescribing daily PrEP
<p><b>If the client acknowledges having had any of the following in the last 3 months:</b></p> <ul style="list-style-type: none"><li>• More than one episode of anal intercourse in the last three months when proper condom use was not achieved (e.g., condom slipped off or broke) where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load</li><li>• (If patient is uncircumcised) more than one episode of insertive CLAI where the serostatus of any partner was not known or was HIV+ and not on treatment or with a detectable viral load</li></ul> <p><b>And:</b></p> <ul style="list-style-type: none"><li>• Being likely to have multiple episodes of CLAI, with or without sharing intravenous drug equipment, in the next 3 months (indicating sustained risk)</li></ul>
C. Low risk – PrEP is not recommended
<p><b>For individuals who:</b></p> <ul style="list-style-type: none"><li>• Have no risk exposure other than CLAI with a partner with documented sustained undetectable HIV viral load in the previous three months. In this setting however, if the HIV-positive partner has recurrent STIs, PrEP may be considered</li><li>• Are circumcised and report practising exclusively insertive CLAI in the last three months.</li></ul>
<p><i>Note: MSM who have only infrequent exposures to HIV (e.g. an occasional broken condom or lapse in condom use) may be good candidates for PEP rather than PrEP. These men, as well as men who fall into low risk category C, should be educated about safer sex strategies, PEP and PrEP, and decisions about PrEP use should be made on a case-by-case basis.</i></p>

## Behavioural eligibility criteria for PrEP for heterosexual people

(Men and women who exclusively have sex with people of the opposite sex)

### A. High risk – recommend prescribing daily PrEP

**If the patient acknowledges having had any of the following in the last 3 months:**

- Being a regular sexual partner of an HIV+ person (not on treatment and/or with detectable viral load) with whom condoms have not been consistently used
- At least one episode of receptive anal or vaginal condomless intercourse with any casual HIV+ partner or a male homosexual or bisexual partner of unknown status
- A female, in a serodiscordant heterosexual relationship, who is planning natural conception in the next 3 months.

**and:**

- Being likely to have multiple episodes of anal or vaginal condomless intercourse, with or without sharing intravenous drug equipment, in the next 3 months (indicating sustained risk)

### B. Medium risk – consider prescribing daily PrEP

**If the patient acknowledges having had any of the following in the last 3 months:**

- At least one episode of receptive anal or vaginal condomless intercourse with a heterosexual partner, not known to be HIV-, from a country with high HIV prevalence

**and:**

- Being likely to have multiple episodes of anal or vaginal condomless intercourse with a heterosexual partner, not known to be HIV+, but at high risk of being HIV+ with or without sharing injecting equipment, in the next 3 months (indicating sustained risk)

### C. Low risk – PrEP is not recommended

**For individuals who:**

- Have no risk exposure other than condomless vaginal intercourse (CLVI) or CLAI with a partner with documented sustained undetectable HIV viral load in the previous three months. However, PrEP may be considered for a HIV- negative female who is trying to conceive with a HIV-positive male
- Are circumcised men who report practicing exclusively CLVI in the last three months.

*Note: Heterosexual men and women who fall into low risk category C, should be educated about safer sex strategies, PEP and PrEP, and decision about PrEP use should be made on a case-by-case basis.*

## Behavioural eligibility criteria for PrEP for people who inject drugs

### A. High risk – recommend prescribing daily PrEP

**If the client acknowledges:**

- being likely to have multiple events of sharing needles or other injecting equipment with a HIV-positive individual, or a homosexually active man, and has inadequate access to safe injecting equipment in the next three months (indicating sustained risk)

**and is:**

- sharing needles or injecting equipment with a HIV-positive individual or with a homosexually active man in the last three months.

*Note: People who inject drugs and do not fall into the high risk category as per the criteria above should be educated about safer injecting and safer sex practices, PEP and PrEP. In these cases, and particularly in populations with a higher proportion of HIV cases due to IDU, such as Aboriginal and Torres Strait Islander people, decisions about PrEP use should be made on a case-by-case basis.*

## Behavioural eligibility criteria for PrEP for trans and gender diverse people

### A. High risk – recommend prescribing daily PrEP

**If the client acknowledges having had any of the following in the last 3 months:**

- Being a regular sexual partner of an HIV+ person (not on treatment and/or detectable viral load) with whom condoms have not been consistently used
- At least **one** episode of receptive anal or vaginal condomless intercourse with any casual HIV+ partner or a male partner of unknown status
- Rectal or vaginal gonorrhoea, rectal or vaginal chlamydia or infectious syphilis diagnosis (during the last 3 months or at screening for PrEP)
- Methamphetamine use, which may increase the risk of HIV acquisition

**and:**

- Being likely to have multiple episodes of anal or vaginal condomless intercourse, with or without sharing intravenous drug equipment, in the next 3 months (indicating sustained risk)

### B. Medium risk – consider prescribing daily PrEP

**If the client acknowledges having had any of the following in the last 3 months:**

- More than one episode of anal or vaginal intercourse when proper condom use was not achieved (e.g. condom slipped off or broke) and where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load
- (If patient is uncircumcised) more than one episode of insertive condomless anal intercourse where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load

**And any of the following is reported:**

- Being likely to have multiple episodes of anal or vaginal condomless intercourse, with or without sharing intravenous drug equipment, in the next 3 months (indicating sustained risk)

*Note: Trans and gender diverse individuals have rarely been included in PrEP studies. As a result, limited data are available for these individuals. Incorrect assumptions can be made about trans people and their sexual practices, although they may practice vaginal/neovaginal (“front hole”) and anal intercourse, or insertive and receptive sex. Trans and gender diverse people who are at high risk of acquiring HIV on the basis of their sexual history are eligible to access PrEP.*

## Appendix 2: Suggested checklist for initiating pre-exposure prophylaxis (PrEP)

**PLEASE NOTE: THE FOLLOWING IS INTENDED AS A GUIDE ONLY.**

Organisation/clinic name

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Print name of doctor

---

Print name of patient

---

Signature of patient

---

Date (day/month/year)

---

### Doctor section

**I have provided this patient with the following: (check all as completed):**

Assessment for possible acute HIV infection	
Assessment of recent HIV risk exposure, within 72 hours (consider post-exposure prophylaxis)	
Indicated laboratory screening to determine indications for these medications	
An HIV risk assessment to determine whether PrEP is indicated for this patient	
A medication fact sheet listing dosing instructions and side effects	
Counselling or a referral for counselling on condom use and any other HIV risk-reduction methods this patient may need	
Advice on methods to help the patient to take medication daily as prescribed	
Information about PrEP use during conception and pregnancy (when indicated)	
A prescription for Truvada (300 mg tenofovir disoproxil fumarate, 200 mg emtricitabine) or equivalent	
A follow-up appointment date	

**As the doctor, I will:**

- Limit refill periods to recommended intervals for repeat HIV testing (at least every 3 months)
- Conduct follow-up visits at least every 3 months that include the following:
  - Assessment of HIV status (including signs or symptoms of acute HIV infection)
  - Assessment of side effects and advice on how to manage them
  - Assessment of medication adherence and counselling to support adherence
  - Assessment of STI symptoms, HIV risk behaviour and counselling for risk-reduction practices
- Inform the patient of any new information about PrEP and respond to questions

## Patient section

### It has been explained to me that:

Taking a dose of PrEP medication every day will lower my risk of getting HIV infection	
This medicine does not completely eliminate my risk of getting HIV infection	
Concurrent condom use will help to protect me against other sexually transmissible infections	
This medicine may cause side effects so I should discuss these at my next visit if I experience any of the side effects	
Even though it is unlikely that I will contract HIV while adhering to my medication, it is important for my health to find out quickly if this happens, so: <ul style="list-style-type: none"><li>I will attend for testing if I have symptoms of possible HIV infection (fever with sore throat, rash, headache, or swollen glands)</li></ul>	
My doctor will test for HIV infection at least once every 3 months	

### Therefore, I will:

- try my best to take the medication my provider has prescribed every day
- talk to my doctor about any problems I have in taking the medication every day
- not share the medication with any other person
- attend all my scheduled appointments
- call \_\_\_\_\_ to reschedule any appointments I cannot attend.

## Give one copy to patient

## Clinical audit

- Patient consents for health information to be used in a de-identified clinical audit:

YES / NO (please circle)

- Record patient's file number on clinical audit sheet

## Patient consent

Signature of patient

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Date (day/month/year)

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# References

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