

Victorian guidance on pre-exposure prophylaxis (PrEP)

August 2016

Acknowledgement

The Victorian Department of Health and Human Services would like to thank the Western Australian Department of Health (WA Health) for giving permission for the use of the document *Guidance on pre-exposure prophylaxis (PrEP) for HIV* August 2015 on which this document is based.

To receive this publication in an accessible format email
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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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ISBN 978-0-7311-7000-5 (pdf/online)

Available at <https://www2.health.vic.gov.au/public-health/preventive-health/sexual-health-and-viral-hepatitis/resources-for-sexual-health-and-viral-hepatitis>

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1. Purpose

This guidance document has been developed to provide medical practitioners with information on antiretroviral pre-exposure prophylaxis (PrEP) for the prevention of human immunodeficiency virus (HIV) transmission. Truvada®, an antiretroviral medication, was approved in Australia for the indication of PrEP in May 2016, but it is yet to be listed on the Pharmaceutical Benefits Scheme. The guidance and information provided in this document is intended to promote understanding amongst medical practitioners about PrEP.

The Department of Health and Human Services recommends that medical practitioners who prescribe PrEP use this guidance document in conjunction with the Sexually Transmissible Infections in Gay Men Action (STIGMA) Group's testing guidelines and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) national PrEP guidelines to ensure a high standard of sexual health care is provided when prescribing PrEP.

2. Background

Antiretroviral medication as a prevention strategy

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, significantly reducing the risk of HIV transmission¹. 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. The Australian Government's *Seventh National HIV Strategy 2014–2017* states that 'treatment as prevention has the potential to produce a population health benefit through reducing community viral load'.²

Antiretroviral treatment as prophylaxis

The use of ART as a prophylactic intervention for HIV infection is already standard clinical practice in Australia, and is used:

- during pregnancy and the perinatal period to prevent mother-to-child transmission of HIV
- in a 28-day course of post-exposure prophylaxis (PEP) to be commenced within 72 hours of exposure, when either an occupational or a non-occupational risk exposure to HIV has been determined.³

However, the use of ART for PrEP in adults who do not have HIV is a relatively new prevention method.

Post-exposure prophylaxis (PEP)

Post-exposure prophylaxis or PEP is the prescription 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).⁴ For patients who repeatedly present for PEP as a result of high risk behaviour, transitioning from NPEP to PrEP, preferably without interruption, would be 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/>).

Pre-exposure prophylaxis (PrEP)

As a prevention method, PrEP involves HIV-negative people using ART to protect themselves from becoming infected with HIV.

This guidance document only refers to oral use of ART, as opposed to other delivery methods such as gels or suppositories or injectables, which are not yet commercially available in Australia.

Clinical evidence on PrEP

In 2012, the World Health Organization (WHO) released preliminary guidance on PrEP. WHO's conditional recommendations on the use of PrEP were based on evidence from clinical trials demonstrating the efficacy of two key ARVs, tenofovir disoproxil fumarate (TDF), and emtricitabine (FTC), in blocking the acquisition of HIV infection in HIV-negative adults.⁵

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

In 2012, the United States Food and Drug Administration approved the use of Truvada for PrEP, and the United States Public Health Service consequently responded with a clinical practice guideline for men who have sex with men and heterosexuals, which they later updated to include people who inject drugs.⁷ 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 86–99 per cent.⁸ For heterosexual women or transgender men having vaginal sex, PrEP must also be taken every day in order to be effective.⁹

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.¹⁰

The PrEP context in Australia

Three Truvada-based PrEP demonstration projects have been operating in Victoria, Queensland, and New South Wales. When these demonstration projects began, Truvada was only approved by the Therapeutic Goods Administration for the indication of treatment and management of HIV infection.¹¹

In February 2015, the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) released clinical practice guidelines for S100 prescribers on prescribing PrEP¹², based on guidelines from the United States Public Health Service⁷. The ASHM guidelines make reference to:

- research evidence about PrEP efficacy 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, Truvada was approved in Australia by the Therapeutic Goods Administration (TGA) for the indication of PrEP. However, until Truvada is listed on the Pharmaceutical Benefits Scheme, cost will be a barrier to access. As a more affordable alternative, many consumers are likely to continue to purchase PrEP from other countries through the internet with an Australian prescription from their doctors.¹³

3. Accessing antiretrovirals for 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 has established a public health research study known as PrEPX, to substantially increase access to PrEP for Victorians at risk of acquiring HIV.

Initially, PrEPX will be accessible through The Alfred Hospital HIV Integrated Prevention Clinic, The Alfred Hospital PrEPX Clinic, the Centre Clinic, PRONTO!, Prahran Market Clinic, Northside Clinic, the Era Health city clinic and the Melbourne Sexual Health Centre. As PrEPX rolls out, the study partners aim to ensure that it is accessible in a range of locations across Victoria.

Although Truvada is now approved for use as PrEP in Australia, affordable access to PrEP remains an issue while it is not listed on the Pharmaceutical Benefits Scheme.

Subsidised PrEP for Victorians can be accessed by enrolling in the PrEPX study which commenced on 26 July 2016.

Alternatively, individuals not enrolled in PrEPX can access antiretrovirals for PrEP by requesting a prescription issued from an Australian-registered medical practitioner, then using this prescription to order a three month supply of a generic formulation of TDF/FTC over the internet, and importing these antiretrovirals under the TGA Personal Importation Scheme.^{13,14} (Note: If the medication is produced by a company other than Gilead Sciences Pty Ltd and imported from overseas, it is considered unapproved therapeutic goods by the Therapeutic Goods Administration.)

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 therefore are prepared to accept any risks associated with taking the medication.¹⁴ 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.

4. Prescribing PrEP

The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) is currently adapting *The Australasian Society for HIV Medicine Australian Commentary: US Public Health Service Clinical Practice Guidelines on Prescribing PrEP* to create standalone Australian PrEP guidelines. The current ASHM guidelines outline behavioural eligibility criteria for men who have sex with men (MSM); heterosexual men and women; and people who inject drugs (PWID).¹² The eligibility criteria are outlined in Appendix 1. It is anticipated that these criteria will be updated in the revised ASHM guidelines.

5. Monitoring sexual health

In Australia, men who have sex with men are disproportionately and increasingly affected by sexually transmissible infections. This has been attributable, in part, to changes in sexual behaviour such as an increase in condomless anal intercourse. As many sexually transmissible infections (STIs) are asymptomatic, regular and frequent STI testing is important to detect infections that may otherwise remain undiagnosed and untreated. The Department recommends that practitioners use the Sexually Transmissible Infections in Gay Men Action (STIGMA) Group's testing guidelines¹⁵ and the Australian STI Management Guidelines for treatment¹⁶ to support a high standard of sexual health care.

6. Guiding principles for prescribing PrEP

For medical practitioners prescribing Truvada or generic co-formulated Tenofovir and Emtricitabine to an HIV-negative patient, there are core guiding principles for developing a patient management plan for PrEP:^{17,18}

- 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 ARVs for 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 they can rely on it being effective, and that women who have receptive vaginal sex and transgender men who have front sex understand that they also need to have taken seven daily doses of PrEP before they can rely on it being effective, based on best available evidence
- 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 sexually transmitted infections (STIs) 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 over a week
- routinely (every three months) screen the patient for STIs, 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.¹⁹ 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"> information on PrEP and conception/ pregnancy short and long-term side effects adherence risk of developing resistance if HIV is acquired 	✓			
Behavioural risk assessment	✓		✓	✓
HIV Ab/Ag combo test	✓		✓	✓
Assessment of acute HIV infection (< 1 month)	✓	✓	✓	✓
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:

- United States Public Health Service *Pre-Exposure Prophylaxis for the infection of HIV infection in the United States –2014: Clinical Providers' Supplement*¹⁸
- World Health Organisation *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV* 2015¹⁰
- ASHM Australian PrEP Guidelines (currently under development); and
- Gilead Sciences Truvada PrEP Resources²⁰.

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**²¹
- Drug information on TDF/FTC²².

(*This template was adapted by the Prahran Market Clinic, Melbourne from a checklist in the United States Public Health Service's *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 whilst on PrEP

Advice on management of a patient who seroconverts to HIV whilst 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 whilst on PrEP:

- a confirmatory HIV test must be conducted
- an HIV genotype test must be conducted
- the patient should be offered a suppressive antiretroviral regimen without ceasing PrEP, in consultation with an HIV specialist²³
- the patient must be linked into HIV care as soon as possible, if the prescriber is not an HIV specialist¹⁷.

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

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 visits²⁴.

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 2015 Australasian Society for HIV Medicine (ASHM) Australian Commentary: US Public Health Service Clinical Practice Guidelines on Prescribing PrEP.

Behavioural eligibility criteria for PrEP for MSM

A. High risk – recommend prescribing daily PrEP
If the client acknowledges: <ul style="list-style-type: none">• being likely to have multiple events of condomless anal intercourse (CLAI), with or without sharing intravenous drug use (IDU) equipment, in the next three months (indicating sustained risk) and having any of the following: <ul style="list-style-type: none">• regular sexual partner of an HIV-infected man with whom condoms were not consistently used in the last three months (HIV-positive partner is not on treatment and/or has detectable viral load)• at least <i>one</i> episode of receptive CLAI with any casual HIV-infected male partner or a male partner of unknown HIV status in the last three months• rectal gonorrhoea, chlamydia and/or syphilis diagnosis during the last three months or at screening• methamphetamine use in the last three months.
B. Medium risk – consider prescribing daily PrEP
If the client acknowledges: <ul style="list-style-type: none">• being likely to have multiple events of CLAI, with or without sharing IDU equipment, in the next three months (indicating sustained risk) And any of the following is reported: <ul style="list-style-type: none">• More than one episode of anal intercourse in the last three months when proper condom use was not achieved (for example, condoms slipped off or broke)• If client is uncircumcised and reports more than one episode of insertive CLAI in the last three months where the serostatus of any partner was not known or was HIV-positive and not on treatment.
C. Low risk – PrEP is not recommended
For individuals who: <ul style="list-style-type: none">• 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• are circumcised and report practising exclusively insertive CLAI in the last three months.
<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>

Behavioural eligibility criteria for PrEP for heterosexual men and women*

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

A. High risk – recommend prescribing daily PrEP

If the client acknowledges:

- being likely to have multiple events of CLAI or condomless vaginal intercourse (CLVI), with or without sharing IDU equipment, in the next three months (indicating sustained risk)

and having any of the following:

- being a regular sexual partner of an HIV-infected man or woman with whom condoms were not consistently used in the last three months (HIV-positive partner is not on treatment and/or has detectable HIV viral load).

B. Medium risk – consider prescribing daily PrEP

If the client is:

- a female, in a serodifferent heterosexual relationship, and is planning natural conception in the next three months.

C. Low risk – PrEP is not recommended

For individuals who:

- have no risk exposure other than 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.

Appendix 2: Checklist for initiating pre-exposure prophylaxis (PrEP)

Organisation/clinic name

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)	
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 support 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">I will attend for testing if I have symptoms of possible HIV infection (fever with sore throat, rash, headache, or swollen glands)	
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

Date (day/month/year)

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