



ashm

Australasian Society for HIV, Viral Hepatitis
and Sexual Health Medicine

Dear Australian Doctor,

RE: Prescription request for HIV PrEP – a HIV prevention antiviral medication

Please assess this patient's suitability for HIV Pre-Exposure Prophylaxis (PrEP). HIV PrEP is the use of antiviral medication by someone who doesn't have HIV in order to protect them from HIV infection. A one pill regimen of tenofovir disoproxil/emtricitabine (TDF-FTC) was listed on the PBS for PrEP in April 2018).

To be eligible for PBS-subsidised PrEP in Australia, a patient needs to be aged 18 years or over and assessed at being at risk of HIV infection according to the ASHM PrEP Clinical Guidelines¹. A tool outlining the assessment process is attached. Individuals who do not meet the eligibility criteria for PrEP, or individuals who do not have access to Medicare/PBS, can be assisted to self-import PrEP under the TGA's personal importation scheme.

In the initial consult, please could you:

- confirm HIV negative status
- screen for hepatitis B, hepatitis C and test kidney function (eGFR/& urine protein/creatinine ratio)
- screen for STIs – treat STIs as required, for more information, see **Australian STI Management Guidelines for Use in Primary Care** website <http://www.sti.guidelines.org.au/>
- Review and update immunisations for HPV, hepatitis A and B and meningococcus
- Measure bone density if there are risk factors for low bone density, and actively monitor

Please write a script for **tenofovir disoproxil 300mg/emtricitabine 200mg daily**. Streamlined Authority 7580 and ask to dispense all repeats.

A follow up appointment in one month's time, and then every three months is required to reassess continuation of PrEP, monitor adherence, test kidney function and test for HIV and STIs.

Important note: If a patient does not have access to medication via Medicare see <https://www.pan.org.au> for advice on how a patient can directly import PrEP.

Yours sincerely,

Associate Professor Mark Bloch; ASHM President

Access further resources and links:

- Access ASHM PrEP Clinical Guidelines (2019) & ASHM PrEP Decision Making Tool at www.ashm.org.au/HIV/PrEP/

1. The Australasian Society of HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) PrEP Guidelines Update. Prevent HIV by Prescribing PrEP. Sydney, 2019.



PRESCRIBING HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) IN AUSTRALIA



1 BEHAVIOURAL SUITABILITY

Patient requests PrEP

Proceed to Step 2

OR

Patient unsure whether to start PrEP or HIV risk identified during consultation

Refer to HIV risks listed overleaf (Table 1)

HIV risk

Low or no HIV risk

Proceed to Step 2

Consider PrEP (e.g. if likely future risk)

Discuss alternative HIV risk reduction methods.

2 CLINICAL SUITABILITY

Note: Steps 1, 2, 3 & 4 are usually completed at the same visit

Confirm HIV status and review medical history including renal function

HIV Negative
(tested within last 7 days)

Assess clinically for acute HIV infection (e.g. fever, night sweats, fatigue, myalgia, arthralgia, rash, headache, pharyngitis, generalised lymphadenopathy, diarrhoea)

Confirm normal renal function (eGFR > 60 mL/min)

Exclude use of nephrotoxic medication (e.g. high-dose NSAIDs) or medications that interact with PrEP www.hiv-druginteractions.org

Proceed to Step 3

HIV Negative
But recent HIV exposure (within 72 hours)

Immediately seek advice on the need for 3-drug nPEP from nPEP hotline on 1800 737 669. If 2-drug nPEP is recommended, prescribe PrEP **with advice for immediate start.**

Plan to commence PrEP upon completion of nPEP course.

Repeat Step 2

HIV Positive

Not for PrEP

Refer to an HIV prescriber (see below)

Clinician resources when making a new HIV diagnosis

www.ashm.org.au/HIV/prevention-testing-and-diagnosis/making-new-diagnosis

List of HIV prescribers: www.ashm.org.au/HIV/HIV-prescribers

3 OTHER TESTING

Assess for STIs and viral hepatitis

STI testing as per the Australian STI Management Guidelines www.sti.guidelines.org.au

Hepatitis B serology (HBsAg, Anti-HBs, Anti-HBc) Vaccinate if not immune If HBsAg+ve, refer to HBV specialist www.ashm.org.au/hbv-prescriber-locator

Hepatitis C serology (anti-HCV; followed by HCV RNA if anti-HCV +ve) If HCV RNA+ve, then treat. www.ashm.org.au/hcvdecisionmaking

Proceed to Step 4

4 PRESCRIBING PrEP

Daily continuous PrEP

Suitable for anyone with an ongoing risk of HIV.

1 pill daily of tenofovir/emtricitabine. Start 7 days before HIV risk.

Proceed to Step 5

OR

On-demand PrEP (2-1-1 method)

Suitable **only** for cis-gender men who have sex with men whose HIV risk is from anal sex rather than injecting drug use. For info on effectiveness, see full ASHM guidelines.

tenofovir/emtricitabine:

- 2 pills at least 2h before sex (up to 24h before sex)
 - 1 pill 24h later
 - 1 pill 48h after first dose
- If repeated sexual activity, then continue with 1 pill daily until 48h after last sexual contact.

Proceed to Step 5

5 ONGOING MONITORING

Ongoing monitoring See Table 2 (overleaf)

&

Patient education
Discuss how PrEP works, frequency, missed dose protocol, continued condom use. See Box 1 (overleaf)

Notes on prescribing PrEP:

- Prescribe: tenofovir 300mg + emtricitabine 200mg (coformulated); 1 tablet daily, Qty 30, Rpt 2.
- PrEP can be initially prescribed on the same day as a HIV test. Patient to be advised to commence PrEP within 7 days of their HIV test.
- PrEP is PBS-listed for patients at medium- to high-risk of HIV.
- PBS streamlined authority: 7580
- Patients not eligible for PBS subsidised PrEP can be assisted to import PrEP under the TGA's self importation scheme, on a private prescription – www.pan.org.au

TABLE 1: HIV RISK

Men who have sex with men (MSM)	Trans & gender diverse people	Heterosexual people	People who inject drugs
<ul style="list-style-type: none"> Receptive CLI with any casual male partner. Rectal gonorrhoea, rectal chlamydia or infectious syphilis. Methamphetamine use. CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load. 	<ul style="list-style-type: none"> Receptive CLI with any casual male partner. Rectal or vaginal gonorrhoea, chlamydia or infectious syphilis. Methamphetamine use. CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load. 	<ul style="list-style-type: none"> Receptive CLI with any casual MSM partner. A woman in a serodiscordant heterosexual relationship, who is planning natural conception in the next 3 months. CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load. 	Shared injecting equipment with an HIV+ individual or with MSM of unknown HIV status.

- If a partner is known to be living with HIV, on antiretroviral treatment and has an undetectable viral load, then there is no risk of HIV transmission from this partner.
- The risks listed above confer a **high risk of HIV**, and hence should prompt a clinician to recommend that a patient start PrEP. However, this list is not exhaustive, and patients who do not report these circumstances may still benefit from PrEP.
- A person is considered to be at "high risk" if they had these risks in the previous 3 months, or if they foresee these risks in the upcoming 3 months.

CLI: Condomless intercourse; MSM: Men who have sex with men.

BOX 1: PATIENT EDUCATION

- Discuss the role of condoms to prevent STIs, and emphasize role of regular STI testing.
 - Discuss safer injecting practices, if applicable.
 - Discuss PrEP adherence at every visit.
 - Ongoing monitoring every 3 months is required.
 - Discuss potential side effects, early (e.g. headache, nausea) and longer term (e.g. renal toxicity, lowered bone density).
 - Ask about nephrotoxic medications, eg NSAIDs.
- STOPPING PrEP:**
- Only cis-gender men who have sex with men (MSM) taking daily or on-demand PrEP can stop 48 hours after last exposure.
 - Non-MSM patients on daily PrEP should continue PrEP for 28 days after last exposure.
 - Patients who stop PrEP need a plan to re-start PrEP if their HIV risk increases again.

TABLE 2: LABORATORY EVALUATION AND CLINICAL FOLLOW-UP OF INDIVIDUALS WHO ARE PRESCRIBED PrEP

Test	Baseline (Week 0)	About day 30 after initiating PrEP (optional but recommended in some jurisdictions)	90 days after initiating PrEP	Every subsequent 90 days on PrEP	Other frequency
HIV testing and assessment for signs or symptoms of acute infection	Y	Y	Y	Y	N
Assess side effects	N	Y	Y	Y	N
Hepatitis A serology, Vaccinate if non-immune	Y	N	N	N	N
Hepatitis B serology Vaccinate if non-immune	Y	N	N	N	Y If patient required hepatitis B vaccine at baseline, confirm immune response to vaccination 1 month after last vaccine dose
Hepatitis C serology	Y	N	N	N	12 monthly but, more frequently if ongoing risk e.g. non-sterile injection drug use and MSM with sexual practices that pre-dispose to anal trauma
STI (i.e. syphilis, gonorrhoea, chlamydia) as per Australian STI Management Guidelines *	Y	N	Y	Y	N
eGFR at 3 months and then every 6 months	Y	N	Y	N	At least every 6 months or according to risk of CKD
Urine protein creatinine ratio (PCR) baseline	Y	N	Y	N	Every 6 months
Pregnancy test (for women of child-bearing age)	Y	Y	Y	Y	N

CKD: chronic kidney disease; eGFR: estimated glomerular filtration rate; PrEP: pre-exposure prophylaxis; PWID: people who inject drugs; STI: sexually transmissible infection

* <http://www.sti.guidelines.org.au/>