

Dear Australian Doctor,

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

Please assess this patient's eligibility 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-FTC0 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 medium to high 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/creatine 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/emtrictabine 200mg daily. Streamlined Authority 7580 and ask to dispense all repeats.

A follow up appointment in one months' 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 (2018) & ASHM PrEP Decision Making Tool at www.ashm.org.au/HIV/PrEP/
- NPS MedicineWise 'Prep on the PBS: An opportunity in HIV Prevention' 16 April 2018 (https://www.nps.org.au/news/prep-on-the-pbs-an-opportunity-in-hiv-prevention)

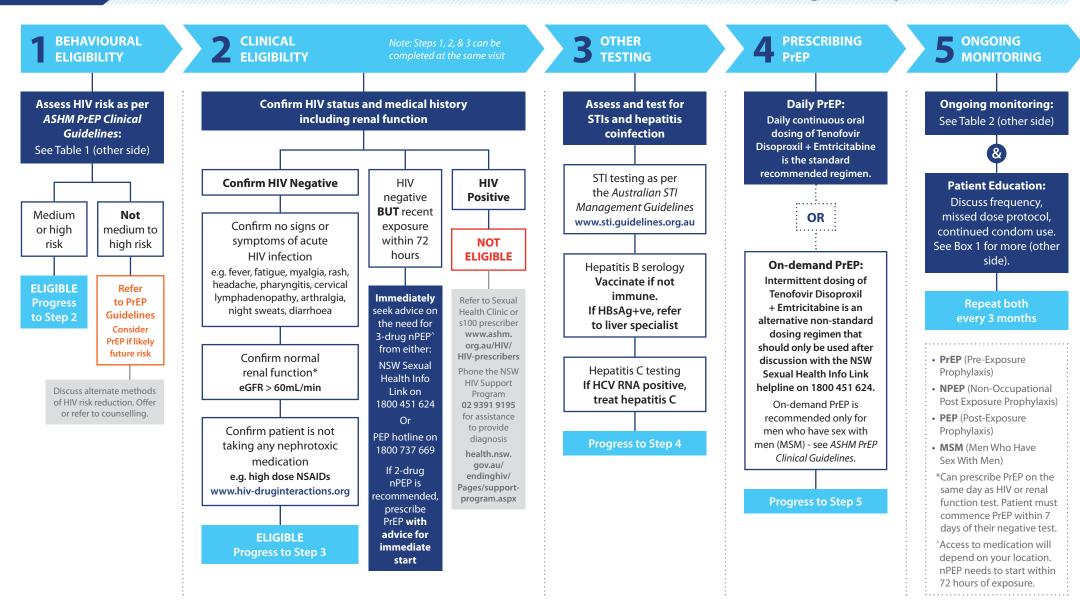
^{1.} Wright E, Grulich A, Roy K, et al. Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines. J Virus Erad 2017;3:168-84



Decision Making in PrEP



Prescribing Pathway for PrEP in NSW



Note: Pre-test counselling for HIV testing not required. Informed consent only needed, see testingportal.ashm.org.au/hiv



Decision Making in PrEP



Prescribing Pathway for PrEP in NSW

Table 1: Behavioural eligibility criteria for PrEP

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|---|--|--|--|--|
| RISK CRITERIA FOR MSM | | | | |
| High Risk – Recommend PrEP | | | | |
| Last 3 months | Next 3 months* | | | |
| CLAI with a regular HIV+ partner (not on treatment and/or detectable viral load) Receptive CLAI with any casual HIV+ male partner or a male partner of unknown status Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis Methamphetamine use Medium Risk - Consider PTEP | t on treatment and/or detectable I load) eptive CLAI with any casual HIV+ e partner or a male partner of incown status tal gonorrhoea, rectal chlamydia or ctious syphilis diagnosis thamphetamine use episodes of CLAI with or without sharing intravenous drug equipment | | | |
| Last 3 months | Next 3 months* | | | |
| Anal intercourse when proper condom use was not achieved (e.g. condom slipped off) where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load If patient uncircumcised: more than one episode of insertive CLAI where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load | | | | |

| RISK CRITERIA FOR TRANS & GENDER DIVERSE PEOPLE | | | | | | | |
|---|---|--|--|--|--|--|--|
| High Risk – Recommend PrEP | | | | | | | |
| Last 3 months | Next 3 months* | | | | | | |
| Regular sexual partner of an HIV+ person (not on treatment and/or detectable viral load) with inconsistent condom use Receptive CLAI with any casual HIV+ partner or a male partner of unknown status Rectal or vaginal gonorrhoea, chlamydia or infectious syphilis diagnosis Methamphetamine use | Multiple episodes of anal or vaginal CLI with or without sharing intravenous drug equipment | | | | | | |
| Medium Risk – Consider PrEP | | | | | | | |
| Last 3 months | Next 3 months* | | | | | | |
| • 1+ episodes of anal or vaginal intercourse when proper condom use was not achieved (e.g. condom slipped off) and where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load of f patient uncircumcised: 1+ episodes of insertive CLAI where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable | • Multiple episodes of anal or vaginal CLI with or without sharing intravenous drug equipment | | | | | | |

| RISK CRITERIA FOR HETEROSEXUAL PEOPLE | | | | | |
|--|---|--|--|--|--|
| High Risk – Recommend PrEP | | | | | |
| Last 3 months | Next 3 months* | | | | |
| A regular sexual partner who is HIV+ (not on treatment and/or with detectable viral load) with inconsistent condom use Receptive anal or vaginal CLI with any casual HIV+ partner, male homosexual or bisexual partner of unknown status A female patient in a serodiscordant heterosexual relationship, who is planning natural conception in the next 3 months | Multiple episodes of CLI with or without sharing intravenous drug equipment | | | | |
| Medium Risk – Consider PrEP | | | | | |
| Last 3 months | Next 3 months* | | | | |
| CLI with a heterosexual partner, not known to be HIV–, from -a country with high HIV prevalence | Multiple episodes of CLI with or without sharing intravenous drug equipment | | | | |

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| RISK CRITERIA FOR PWID | | | | | |
|--|--|--|--|--|--|
| High Risk – Recommend PrEP | | | | | |
| Last 3 months | Next 3 months* | | | | |
| • Shared injecting equipment with an HIV+ individual or with a gay or bisexual man of unknown HIV status | Multiple events of sharing injecting equipment with an HIV+ individual or a gay or bisexual man of unknown HIV status Inadequate access to safe injecting equipment | | | | |

- **PWID** (People Who Inject Drugs)
- CLI (Condomless Intercourse)
- CLAI (Condomless Anal Intercourse)
- *Is the patient **likely** to behave like this in the next 3 months (indicates a sustained risk)

Table 2: Laboratory evaluation & clinical follow-up of individuals who are prescribed PrEP

| Test | Baseline | ±30 days after initiation | 90 days after initiation | Every 90 days on PrEP | Other frequency (minimum) |
|---|----------|------------------------------|-----------------------------|--------------------------|---------------------------------|
| HIV testing and assessment for signs or symptoms of acute infection | V | V | ~ | V | n/a |
| Assess side effects | n/a | ✓ | ✓ | ✓ | n/a |
| Hepatitis B serology | ✓ | n/a | n/a | n/a | n/a |
| Hepatitis C serology | ✓ | n/a | n/a | n/a | Every 12 mths |
| STI (i.e. syphilis, gonorrhea, chlamydia) as per Australian STI Management Guidelines | V | n/a | ~ | V | n/a |
| eGFR \pm urine protein: creatinine ratio (PCR) at 3 mths $\&$ then every 6 mths | V | n/a | ~ | n/a | Every 6 mths |
| Pregnancy test (women of child-bearing potential) | V | ✓ | ✓ | V | n/a |

viral load

Box 1: Patient Education

- Discuss HIV-risk behaviours
- Discuss combination HIV/STI prevention, including the central role of condoms
- Discuss safer injecting practices if applicable
- Check mental health and recreational drug use
- Patients need to take a daily dose of PrEP for 7 days to achieve high levels of protection, 20 days to achieve maximum protection
- If stopping PrEP patients on daily PrEP should continue PrEP for 28 days following exposure
- Ongoing monitoring every 3 months is required see Table 2; discuss potential side effects include early e.g. headache, nausea and long term e.g. renal injury, lowered bone density
- If a patient misses a dose, they should take the missed dose as soon as they
 remember it. If it is less than 12 hours until the next scheduled dose, the patient
 should skip the missed dose and continue with the regular dosing schedule