



# 1. Introduction

Widespread availability and uptake of human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) has the potential to significantly reduce HIV transmission in Australia and globally.

Co-formulated tenofovir and emtricitabine for use as HIV pre-exposure prophylaxis (PrEP) by people at risk of HIV infection is now recommended as standard care in clinical guidelines in the United States of America, Europe and Australia ([1, 2, 3](#)), as well as globally through World Health Organization (WHO) guidelines ([4](#)). When used with optimal medication adherence, daily PrEP is a highly effective HIV prevention strategy for men who have sex with men (MSM), heterosexual men and women, transgender people, and people who inject drugs who are at-risk of HIV acquisition ([5-11](#)). In addition, on-demand PrEP is highly effective in MSM ([12-14](#)) and has recently been recommended by the World Health Organisation as an option for MSM ([15](#)).

These clinical PrEP guidelines update the 2018 ASHM PrEP guidelines ([3](#)) which were initially an adaptation and update of the 2014 United States Centers for Disease Control's PrEP guidelines ([16](#)).

On May 2016, the Australian Therapeutic Goods Administration (TGA) approved the entry of Truvada (co-formulated tenofovir disoproxil fumarate and emtricitabine TDF/FTC; Gilead Sciences) onto the Australian Register of Therapeutic Goods (ARTG) for HIV PrEP for people at risk of HIV infection. Since then, a number of generic co-formulations of tenofovir disoproxil\* and FTC have been registered by the TGA for HIV PrEP (for simplicity, TD\* is used in these guidelines to denote the tenofovir disoproxil component present in the medicines registered for PrEP use in Australia).

From 1 April 2018, the brand and generic versions of TD\*/FTC became available through the Australian Pharmaceutical Benefits Scheme (PBS) at subsidised cost for HIV PrEP ([17](#)). Whereas previously PrEP was available only through clinical trials, private scripts or through personal importation, it can now be prescribed by all general practitioners (GP) and authorised nurse practitioners using PBS scripts. People with Medicare numbers can fill their scripts through the PBS, however people who are Medicare ineligible can either legally import generic PrEP using the TGA Personal Importation Scheme (PIS) ([18](#)), or pay the full price with a private script.

## **The recommendations in these guidelines are designed to:**

- support the prescribing of PrEP using either ARTG-listed and PBS subsidised drugs, or the same or other generic drugs that are available through personal importation, or by paying the full price with a private script
- assist clinicians in their evaluation and HIV risk assessment of patients who are seeking PrEP
- assist clinicians in initiating their patients on PrEP by providing information on PrEP dosing schedules
- assist clinicians in the monitoring of patients on PrEP, including testing requirements and management of side-effects and toxicity

- assist clinicians to be aware of more complex situations such as the use of PrEP in pregnancy and in chronic hepatitis B infection
- assist clinicians in understanding how to safely cease PrEP.

**These guidelines are intended for use by:**

- general practitioners who provide care to people at risk of acquiring HIV infection
- sexual health physicians and ID physicians who provide care to people at risk of acquiring HIV infection and/or who serve as consultants to primary-care physicians about the use of ARV antiretroviral treatment
- infectious disease and HIV treatment specialists who may provide PrEP for, or serve as consultants to primary-care physicians about the use of antiretroviral medications
- trainees and registrars in each of the above categories
- authorised nurse practitioners who provide care to people at risk of acquiring HIV infection
- nurses working in nurse-led clinics in consultation with doctors
- peer workers
- counsellors and people performing HIV testing, including point-of-care testing
- health program policymakers
- health consumers and others with an interest in HIV PrEP.

**Key recommendations of the ASHM PrEP Guidelines Panel**

**The ASHM PrEP Guidelines Panel recommends that daily TD\*/FTC should be recommended by clinicians as a crucial HIV-prevention strategy for all people who are at risk of HIV infection, that is, men who have sex with men (MSM), transgender people, heterosexual men and women, and people who inject drugs.**

**The ASHM PrEP Guidelines Panel endorses the recent recommendation by WHO that on-demand PrEP should be offered to cis-gender MSM ([15](#)).**

On-demand PrEP is recommended only for cis-gender MSM because its efficacy is yet to be determined in all other populations at risk of HIV infection. On-demand PrEP would be a suitable choice for cis-gender MSM who express a preference for on-demand PrEP, who have at-risk sex less than twice a week and who can plan ahead for at-risk sex at least 2 hours in advance.

The ASHM PrEP Guidelines Panel recommends that caution be used in recommending on-demand versus daily PrEP to adolescent MSM because there have been no trials of on-demand PrEP in adolescent MSM and because adherence rates to daily PrEP have been consistently low in studies of adolescent MSM ([19](#), [20](#)).

**On-demand PrEP is contraindicated in people with chronic hepatitis B infection.**

Of note, the Panel will continue to monitor the data on the efficacy of on-demand PrEP for MSM who use on-demand PrEP less frequently than fortnightly ([14](#), [21](#)).

## References

1. US Preventive Services Task Force; Owens DK, Davidson KW, Krist AH, et al. Preexposure prophylaxis for the prevention of HIV infection: US Preventive Services Task Force Recommendation Statement. *JAMA* 2019;321:2203-13.
2. European AIDS Clinical Society (EACS) guidelines for the treatment of HIV-positive adults in Europe. Version 9.1, October 2018. Available at: <http://www.eacsociety.org/guidelines/eacs-guidelines/eacs-guidelines.html> (last accessed 18 July 2019).
3. Wright E, Grulich A, Roy K, Boyd M, Cornelisse V, Russell D, et al. Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines. Update April 2018. *J Virus Erad* 2018;4:143-59.
4. World Health Organization. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. September 2015. Available at: <https://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/> (last accessed 9 September 2019).
5. Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363:2587-99.
6. Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399-410.
7. Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* 2012;367:423-34.
8. Anderson PL, Glidden DV, Liu A, et al; iPrEx Study Team. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Sci Transl Med* 2012;4:151-68.
9. Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381:2083-90.
10. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis* 2014;14:820-9.
11. McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet* 2016;387:53-60.
12. Molina JM, Capitant C, Spire B, et al; ANRSIPERGAY Study Group. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med* 2015;373:2237-46.
13. Molina JM, Charreau I, Spire B, et al; ANRS IPERGAY Study Group. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *Lancet HIV* 2017;4:e402-10.
14. Molina JM, Ghosn J, Algarte-Génin M, et al; ANRS Study Group. Incidence of HIV-infection with daily or on-demand PrEP with TDF/FTC in Paris area. Update from the ANRS Prévenir Study. Abstract TUAC0202. Oral abstracts of the 10th IAS Conference on HIV Science, 21-24 July 2019, Mexico City, Mexico. *J Int AIDS Soc* 2019;22 Suppl 5:e25327.

15. World Health Organization. Technical brief. What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP. July 2019. Available at: <https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf?ua=1> (last accessed 3 September 2019).
16. US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014. A clinical practice guideline. Atlanta: Centers for Disease Control and Prevention; 2014.
17. PrEP on the PBS: an opportunity in HIV prevention. 16 April 2018. Available at: <https://www.nps.org.au/news/prep-on-the-pbs-an-opportunity-in-hiv-prevention> (last accessed 3 September 2019).
18. Australian Government. Department of Health. Therapeutic Goods Administration. Personal importation scheme. 2015 [internet]. Available at: [www.tga.gov.au/personal-importation-scheme](http://www.tga.gov.au/personal-importation-scheme) (last accessed 4 September 2019).
19. Hosek SG, Rudy B, Landovitz R, et al; Adolescent Trials Network (ATN) for HIVAIDS Interventions. An HIV preexposure prophylaxis demonstration project and safety study for young MSM. *J Acquir Immune Defic Syndr* 2017;74:21-9.
20. Hosek SG, Landovitz RJ, Kapogiannis B, et al. Safety and feasibility of antiretroviral preexposure prophylaxis for adolescent men who have sex with men aged 15 to 17 years in the United States. *JAMA Pediatr* 2017;171:1063-71.
21. Antoni G, Tremblay C, Charreau I, et al. On-demand PrEP with TDF/FTC remains highly effective among MSM with infrequent sexual intercourse: a sub-study of the ANRS IPERGAY trial. Abstract TUAC0102. 9th International AIDS Society (IAS) Conference on HIV Science. July 2017; Paris, France.