

HERE FOR HEALTH

SUBMISSION TO:

**The Pharmaceutical Benefits Advisory Committee
Truvada as Pre-Exposure Prophylaxis (PrEP)**

June 2016



About ACON

ACON is New South Wales' leading health promotion organisation specialising in HIV prevention, HIV support and lesbian, gay, bisexual, transgender and intersex (LGBTI) health. Established in 1985 as the AIDS Council of NSW, our mission is to enhance the health and wellbeing of our communities by ending HIV transmission among gay and homosexually active men, and promoting the lifelong health of LGBTI people and people with HIV.

General Comments

ACON welcomes the opportunity to provide you with information relating to the availability of PrEP in Australia.

We write in support of the submission made by Gilead supporting the change to the listing of Tenofovir with Emtricitabine (Truvada™) on the Pharmaceutical Benefits Scheme (PBS) to recognise its use as HIV pre-exposure prophylaxis (PrEP). We would like to provide commentary focusing on a number of points from the perspective of Australia's largest HIV and LGBTI health organisation.

We also fully endorse the submission made by the Australian Federation of AIDS Organisations (AFAO).

We strongly welcomed the listing of Truvada as PrEP on the Australian Register of Therapeutic Goods (ATRG). This decision reinforced what we already knew to be true, that Truvada is safe and efficacious when used to prevent the sexual transmission of HIV.

PrEP is an important tool for gay men, including transgender gay men, in Australia and we, as a community, are ready for this. It will provide an additional tool to the existing suite of available strategies to reduce the transmission of HIV in Australia. Along with treatment as prevention, condoms and risk reduction strategies, PrEP is vitally important to achieve the goal to virtually eliminate new HIV transmissions by 2020, as articulated in the Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS, the 7th National HIV Strategy and the NSW HIV Strategy 2016-2020.

Issues for Consideration

(a) Importance of PrEP for HIV Prevention

Listing Truvada on the PBS for use as PrEP is the vital next step in ensuring that Australians have access to the full range of proven biomedical strategies to prevent HIV transmission.

The data from the results of a multitude of recent international studies have shown that Truvada as PrEP is highly effective. The *iPrEX*ⁱ, *IPERGAY*ⁱⁱ and *PROUD*ⁱⁱⁱ studies have provided strong evidence that PrEP is at least 86% effective for gay and other homosexually active men (GHAM) when used correctly. The level of efficacy shown in these studies gives us the confidence that PrEP will be an important tool in the prevention of HIV in Australia.

The *World Health Organisation*, in its updated *Guidelines On HIV Prevention, Diagnosis, Treatment And Care For Key Populations*, released on 11 July 2014 'strongly recommends men who have sex with men consider taking antiretroviral medicines as an additional method of preventing HIV infection (pre-exposure prophylaxis) alongside the use of condoms'^{iv}.

Australia has had a strong and effective response to HIV over the last 30 years. The use of prevention methodologies such as condoms and treatment as prevention, as well as comparatively high rates of sexual health testing has meant that the Australian epidemic remains relatively contained. However, the existing measures have not been sufficient and the listing of Truvada for use as PrEP on the PBS is essential to achieve the goals of the *7th National HIV Strategy* and the *NSW HIV Strategy 2016-2020*.

The listing of Truvada as PrEP on the ARTG was only the first step; it showed that the government recognised the safety and efficacy of PrEP. We are pleased that the PBAC is able to assess this change to the listing on the PBS so promptly, as to leave it only to those who can afford the unsubsidised price is unfair and would significantly limit its potential impact.

The listing of Truvada on the PBS for use as PrEP will ensure that our health care system is able to provide the high quality healthcare that it was set up to deliver.

(b) Knowledge and Engagement with PrEP

Knowledge about PrEP has been growing in NSW, from a small base when the Sydney Gay Community Periodic Survey (2013)^v first asked questions on this topic, through to the enrolment of over 1300 high risk men in the EPIC study^{vi}. Much work has been done by community organisations and gay men themselves to become aware and educated about PrEP.

We know that gay men are comfortable and confident in their use of other preventative measures and most will continue to use them without a need or desire for PrEP. Gay men are highly literate about HIV and continue to show this through their selective uptake of the prevention strategies that are most appropriate for them, and their current situation.

We don't envisage the majority of gay men taking up PrEP, but in the studies undertaken in Australia and around the world, those who will benefit most have been shown to be highly engaged and interested.

Here in NSW the Prelude Study, which involves 300 people utilising PrEP, was designed to look at how PrEP can be implemented in NSW. It will also examine whether the target populations in NSW find PrEP easy and agreeable to take every day as well as the impact of PrEP on users, focusing on why they take it and what impacts it has on behaviour. Additionally it investigates the experience of doctors and what resources are necessary to make PrEP available.

As of March 2016 enrolment into the EPIC-NSW study has begun, with over 1300 people already enrolled as at May 2016. The aim of EPIC-NSW is to assess the impact of the rapid scale-up in access to PrEP amongst those at highest risk of acquiring HIV in NSW. The interest in this study amongst those people who would most benefit from PrEP has been high, and has shown that when our communities are presented with information and access to a proven prevention technology, that it is taken up.

In order to access affordable PrEP we have seen some gay men personally importing PrEP, which raises a number of concerns and has a number of limitations. Although a script is required from a clinician, we have seen evidence that in some cases, the ongoing health monitoring and sexual health testing has not been occurring in the way that it should. Additionally, this parallel system of access has a number of implications for the monitoring and surveillance of the HIV response in Australia.

Gay men and others at risk of HIV have embraced this knowledge and acted promptly. We know that those who need PrEP want it and will use it in an informed way.

(c) Implementation and Access

These existing Australian studies and self-importation are workarounds and inferior options compared to full access through standard channels. However, the experience of implementing these trials has ensured that both health care systems and the community itself are ready to implement access to PrEP in a targeted way.

Affected communities, researchers, clinicians and government have identified and sought to address the barriers to access and the use of PrEP. The listing of Truvada for use as PrEP on the PBS is one of the final barriers and essential before further targeted community education can be undertaken. The resources utilised during the recruitment for the Australian studies have been developed in a way that will ensure they can be easily and quickly modified for use once PrEP is available on the PBS.

Having achieved listing on the ARTG, the major remaining barrier for most people to accessing PrEP is cost and this must be addressed. We would stress the importance of the whole process, including any approvals by Cabinet, being finalised before the trials end otherwise people would be left without appropriate access to PrEP.

In addition, by ensuring that PrEP is accessible through normal channels in Australia, the number of people utilising personal importation will decrease, which will help ensure that they are linked to appropriate information and care.

ACON supports the clinical criteria put forward by AFAO in their submission:

“Truvada for PrEP should be offered to any person who is assessed as being at high risk of acquiring HIV infection, taking into account risk factors arising from condomless anal or vaginal sex or injecting drug use.”

Further, guidance for clinicians to ensure that PrEP is appropriately targeted to those in need can be provided through organisations such as ASHM.

Most gay men access their primary healthcare, including their sexual health care, via their local GP rather than with an authorised s100 HIV prescriber. If PrEP is to be targeted to people most at risk of acquiring HIV, there must be no unnecessary barriers to obtaining a prescription. Access to s100 prescribers is limited outside of larger population centres, including in regional and rural NSW, as well as in other states and territories.

The prescribing of PrEP is not clinically complex, therefore the prescribing of PrEP should not be restricted to accredited s100 HIV treatment clinicians. To do so would be a major barrier to access, particularly for people outside of inner-city areas where these types of prescribers tend to be concentrated.

Additionally, many in our community have strong connections with their local GPs for both sexual and general health needs and not all of these doctors will be s100 prescribers. An unnecessary restriction of prescribing to current s100 arrangements would disrupt pre-existing care relationships. For both the individual and public health benefits of PrEP to be maximised, broader prescribing arrangements are a necessary.

The recent expansion of dispensing of HIV medications to community pharmacies has been successful and has the benefits of providing greater flexibility for the consumer and to reduce the pressure on hospital pharmacies. In light of this success, PrEP should also be dispensed through community pharmacies.

We have seen the negative impact that delays, through the regulatory system, have had on the access to treatment for people living with HIV and the negative impact that this can have on the health and wellbeing of individuals and the community. Our communities have mobilised to ensure that the same delays do not happen with PrEP. We have recently seen the importance of timely access with the approval of hepatitis C drugs and hope that the PBAC will move quickly on PrEP too.

Concluding remarks

It is internationally recognised that the Australian response to HIV has been world leading. Australia is best placed to be the first country to achieve the international goal of no new HIV infections by 2020.

The community is ready to add PrEP to the toolbox of preventative measures. Yet without altering the listing of Truvada on the PBS, this will not be accessible to those who need it and who will benefit most.

As a sector we are primed to implement PrEP, and all that is necessary to make sure that it delivers the potential that rigorous scientific investigation has shown that the drug holds. Clinicians are ready to provide the baseline testing and ongoing monitoring for those who utilise PrEP. The community sector is ready to adapt existing community education to a wider audience. Government, through its commitment at all levels to the goal of the virtual elimination of new infections by 2020, has shown it is ready.

We strongly urge the PBAC to recommend altering the current listing for Truvada to include its use as

PrEP on the PBS.

ⁱ Grant RM et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *New Engl Jour Med* 363(27):2587-2599, 2010

ⁱⁱ Molina J-M et al. On Demand PrEP With Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial. 2015 Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, USA, abstract 23LB, 2015.

ⁱⁱⁱ McCormack S et al. Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study. 2015 Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, USA, abstract 22LB, 2015.

^{iv} <http://www.who.int/hiv/pub/guidelines/keypopulations/en/>

^v Hull, P., Mao, L., Kao, S.-C., Edwards, B., Prestage, G., Zablotska, I., de Wit, J., & Holt, M. (2013). *Gay Community Periodic Survey: Sydney 2013*. Sydney: National Centre in HIV Social Research, UNSW Australia.

^{vi} http://www.health.nsw.gov.au/news/Documents/20160520_00.pdf