New Zealand AIDS Foundation
Te Tūāpapa Mate Āraikore o Aotearoa

PHARMAC
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1 June 2022

Tēnā koe PHARMAC,

Feedback on the proposed changes to funding of emtricitabine with tenofovir disoproxil for pre-exposure prophylaxis of HIV (PrEP) and antiretrovirals for post-exposure prophylaxis of HIV (PEP)

We are writing in response to PHARMAC's proposal to widen the criteria for both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) of HIV. We are in full support of the spirit and direction of PHARMAC's proposed changes. Along with condoms, regular screening, and early linkage to care, PrEP and PEP are cornerstones of the highly successful combination approach to HIV prevention. We know that the effectiveness of biomedical prevention tools depends on sufficient scale of their use among those at disproportionate risk of HIV acquisition (1). We also know that Aotearoa must significantly scale up our HIV prevention measures, including PrEP, if we are to meet the UNAIDS target of 90% reduction of new HIV infections by 2030 (compared to the 2010 baseline) that we have committed to (2, 3). As such, we welcome PHARMAC's proposal to expand the existing eligibility criteria of PrEP and PEP, as these are known barriers to access. In this submission, we also include recommendations that will help ensure that the criteria are safe and appropriate for patients and clinicians, as well as ensure that PrEP and PEP are available to the populations that would benefit from them most.

The New Zealand AIDS Foundation (NZAF) is a registered charity and non-governmental organisation funded through contracts with the Ministry of Health and independent fundraising to provide a range of HIV and AIDS related services, including HIV prevention and health promotion, HIV testing, counselling and support, research, policy, and information services. NZAF advocates for healthy public policy and environments that support our communities, those most affected by HIV.

1. Emtricitabine with tenofovir disoproxil for pre-exposure prophylaxis of HIV (PrEP)

Overall, we are pleased to see the changes that have been proposed for the PrEP criteria. These changes remove some of the key barriers to accessing PrEP and will enable more people who need PrEP to access it. Our key recommendations include adding a criterion that ensures the clinician is familiar with relevant New Zealand clinical guidance and has ensured that prescribing and patient monitoring is appropriate as per local clinical guidance, including a reference to the up-to-date NZ Commentary to ASHM guidance, and clarifying the language surrounding monitoring the risk of seroconversion.

We support the removal of all criteria regarding history of inconsistent condom use and the need to specify receptive anal intercourse. These criteria required disclosure of intimate details of personal sexual practices which is a well-known barrier to accessing PrEP. According to unpublished NZAF Ending HIV Evaluation Survey data, 45.1% of GBM at increased risk of HIV acquisition

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(reporting condomless anal intercourse with a casual partner in the previous 6 months) and not on PrEP felt uncomfortable discussing PrEP with a doctor or nurse. Half of gay and bisexual men in New Zealand are not open with their GP about their sexual orientation or behaviour (4). Local research has shown that this barrier regarding disclosure to healthcare providers is exacerbated for Asian gay and bisexual men (4, 5). Patients may face additional stigma or shame from needing to disclose receptive anal intercourse (6). Given this wealth of evidence, we are in full support of removing the criteria that require individuals to disclose sensitive details of stigmatised sexual behaviour in order to access preventative healthcare.

We also believe that these changes may help improve equity of PrEP uptake for Māori. Unpublished NZAF Ending HIV Evaluation Survey data showed that while less Māori reported current use of PrEP compared to the sample average (16.9% vs 19.4%), the percentage of those who wanted to use PrEP was higher among Māori participants (68.6% vs 60.5%). This indicates that Māori may face barriers to PrEP access despite high acceptability of this prevention method. Nearly half of Māori participants who were not using PrEP in our survey felt that discomfort discussing PrEP with a doctor or nurse prevented them from accessing PrEP. This barrier was more commonly reported among Māori as compared to other ethnic groups. We believe that removing the need to discuss personal sexual behaviour in detail will help address this barrier, ultimately facilitating access to PrEP among Māori. Māori participants also reported three monthly prescription renewal as a barrier more than other ethnic groups. While this specific barrier will not change along with the criteria change, ensuring that these visits are less invasive is likely a step in the right direction.

We also note that the removal of criteria specifying receptive anal intercourse will lead to more consistent health promotion messaging to communities. The previous criteria created a two-tier hierarchy of risk between receptive and insertive anal intercourse which was difficult to communicate and caused confusion among our communities. Many members of the GBM communities found it difficult to understand that while insertive anal intercourse carries high risk of HIV transmission, they are not eligible for funded PrEP as prevention.

We wish to note that, concerningly, unpublished NZAF Ending HIV Evaluation Survey data showed that 21.4% of GBM not on PrEP who reported condomless anal sex with casual partners, did not believe they met the previous PrEP eligibility criteria. This perceived ineligibility was one of the top three barriers to PrEP access. Data from the same survey also revealed that a quarter of those not willing to start PrEP who reported condomless anal sex with casual partners believed that they did not put themselves at risk and so did not need PrEP. We believe that the simplification of the PrEP eligibility criteria will help to address these inaccurate perceptions of personal eligibility or risk among our communities, leading to more PrEP uptake in the future among those at significant risk of HIV transmission.

We support the removal of criteria that require patients demonstrate previous risk in the past three months. This change brings Aotearoa in line with the New Zealand ASHM guidance that recommends considering clinical situations where PrEP may be used effectively to reduce the risk of HIV (7). Previous PHARMAC criteria required disclosure of history of risk, which may be challenging to the patient. Reporting detailed sexual history may also be incomplete or biased due to shame or lack of recall, therefore presenting a barrier to effective PrEP access. History of risk criterium was also unnecessarily restrictive for patients who, for a variety of reasons, failed to demonstrate previous risk but were likely to be at risk in the future. These reasons could include young age (i.e. no sexual history), change in relationship status, or planned future travel. It was also inappropriate

that eligibility for preventative healthcare like PrEP required previous exposure to risk, especially considering PrEP is no longer the highly scarce and expensive medication it was at the time of initial funding in Aotearoa. Thus, the removal of these criteria helps ensure that people do not feel that they must engage in condomless anal intercourse in order to be eligible for PrEP.

We support the renewal period for special authority being changed from three months to 24 months. It is our understanding that this extension refers to funding approval only, not prescription length and the latter will continue to be provided in three-monthly intervals. We believe this is appropriate due to low cost of PrEP and avoidance of unnecessary administrative tasks for clinicians who no longer will have to justify seeking approval for funding at short intervals.

We acknowledge the removal of HIV and other STI testing from the PHARMAC criteria for PrEP funding eligibility. We note that this will bring PrEP in line with funding criteria for most other medications, where monitoring guidelines are not included as part of the funding criteria, but continue to be required as part of clinicians' best practice. We also understand that patients are still required to have tested negative for HIV at time of renewal in order to be eligible for the subsidy, indicating the critical importance of HIV screening before prescription. We strongly believe it is essential that patients receive appropriate and regular clinical monitoring (that includes currently recommended three-monthly HIV and STI screenings) and we understand this can be effectively regulated at the level of clinical guidance. We note that since the initial funding of PrEP, New Zealand local clinical guidance has been published , along with other resources to guide PrEP prescribing (7). These include the NZAF/ASHM PrEP flowchart, Health Pathways guidance, BPAC resource, and others (8-10). PHARMAC data shows that over 1000 prescribers in primary care have prescribed PrEP at least once in 2021, which suggests that familiarity with this method of prevention is growing. We support PHARMAC in working with other key agencies (Medsafe, MoH, regional clinical governance bodies) to conduct regular clinical auditing and education to address any inappropriate prescribing. We are confident that NZAF and NZ Sexual Health Society are able to support PrEP education, if appropriately resourced.

We recommend adding a criterion that ensures "the clinician is familiar with relevant New Zealand clinical guidance and has ensured that prescribing is clinically indicated and patient monitoring is appropriate as per local clinical guidance". We also recommend including a specific reference to the up-to-date NZ-ASHM guidance. In general, we are supportive of initiatives that enable clinical discretion in prescribing PrEP. This is important given the wide range of situations where PrEP may be beneficial to a patient, where HIV risk is present as a result of unique circumstances (e.g., heterosexual patients travelling to a high-prevalence country where they anticipate condomless sex). We acknowledge the concerns of some clinicians with regards to the 'purview paradox' in which it is recognised that PrEP should be delivered at scale through standard primary care, but it is also perceived that primary care may not be currently equipped to do this in a competent manner (11, 12). PrEP use should always be guided by evaluation of risks and benefits for the given patient. Available clinical guidelines offer frameworks to effectively weigh these and identify scenarios where PrEP offers a clear HIV prevention benefit in patients belonging to different population groups and engaged in diverse sexual networks. The guidelines also offer detailed monitoring requirements that can effectively guide clinical practices. NZAF is also currently preparing an educational module to support appropriate PrEP prescribing for primary care physicians. Therefore, while we note that there is a risk of PrEP overprescribing in certain scenarios (e.g., GBM only engaging in oral sex, or most heterosexual patients), this can and should be managed by the clinician in accordance with the clinical guidance. We hope that Including the above criterion will help further safeguard against any instances of incorrect prescribing of PrEP and point clinicians who are not yet familiar with PrEP in

the direction of appropriate guidance. A significant advantage of the addition of this criterion is that the local clinical guidelines can be updated frequently, ensuring dynamic responsiveness to the changing epidemiology and evolving knowledge of the biomedical prevention landscape for HIV. **We recommend changes to the wording of criteria 1. We propose: "Patient has tested HIV negative, does not present with symptoms consistent with acute HIV infection, and has been assessed for risk of seroconversion".** Many patients at the highest risk of HIV acquisition, may be at continuous or frequently recurring risk of seroconversion. We believe that this risk needs to be assessed and patients need to be evaluated appropriately. In some cases, this requires more frequent testing and monitoring for symptoms. Current clinical guidance recommends that PrEP should not be initiated in those at risk of seroconversion who present with symptoms consistent with acute retroviral infection. However, for those who are at risk of seroconversion due to recent high-risk exposure but present with no signs of acute retroviral infection and are likely to have continued exposures, PrEP initiation should not be delayed until this risk is excluded. Delaying PrEP initiation in such cases could result in the persistence of increased risk for these individuals. If the most recent exposure was within the previous 72 hours, PEP can be initiated and then transitioned to continuous PrEP if ongoing exposures are likely, and detailed clinical guidance can be used to manage this process.

2. **Antiretrovirals for post-exposure prophylaxis of HIV (PEP)**

We are pleased to see the changes that have been proposed for the PEP criteria, as we believe the widening of prescribers and eligibility criteria will help reduce barriers to uptake of PEP. However, we recommend replacing criteria 2.1 and 2.2 with one criterion that includes patients who have had unprotected anal intercourse or vaginal intercourse with a known HIV positive person with an unknown or detectable viral load (> 200 copies per ml) or with a person from a high HIV prevalence country or risk group whose HIV status is unknown. We also recommend removing the "Notes" section given the heteronormative and cisnormative assumptions in its definition of vaginal intercourse.

We support PHARMAC's proposal to widen the PEP prescriber group to any relevant practitioner. This will improve access as widening prescribers helps address inequities in geographic availability of named antiretroviral specialists. Significant geographic coverage issues persist, and we hope the changes will help improve access in places like Queenstown, where the nearest hospital is a four-hour drive and there are no named antiretroviral specialists (13). Furthermore, we hope that the changes will reduce wait times for time-sensitive access to PEP. In addition, under the current system, patients who do not receive ongoing care from their emergency department doctor and have not established a trusting rapport with them must disclose intimate parts of their sexual life in order to access PEP. Relaxing the restriction in the number of prescribers provides more options to patients, and enables them to choose a provider they are comfortable with. This may help remove the barriers around disclosure.

We support the removal of the need to specify receptive anal intercourse in criterion 2.1. We support this change, as it ensures the threshold for eligibility for PEP is reasonable, which in turn ensures that at-risk groups have access. It also helps remove the barrier of needing to disclose intimate details of sexual practices with clinicians in order to access PEP.

We recommend replacing criteria 2.1 and 2.2 with the following: "Patient has had unprotected anal intercourse or vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml or with a person from a high HIV prevalence country or risk group whose HIV status is unknown". We also insist on the removal of the "Notes" section that specifies that "unprotected receptive vaginal sex" in criterion 2.1 refers to intercourse between an HIV-positive male and a HIV-negative female. We agree with the Anti-Infective PTAC subcommittee that limiting PEP eligibility to those who have sex with known HIV positive people only, who are likely on treatment with an undetectable viral load, is no longer relevant (Anti-Infective Subcommittee of PTAC, 2019). As noted by the subcommittee (Anti-Infective Subcommittee of PTAC, 2019), the current PEP criteria are not in line with the latest evidence that a significant proportion of HIV transmission is driven by those who are not aware they have HIV (14, 15). Therefore, we welcome the proposed expansion of the eligibility criteria to include unprotected intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown. We also suggest clinicians rely on tools such as the ASHM PEP guidance to assess risk (16).

We recommend including "vaginal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown" in the criteria as this allows all cisgender women, transgender people, nonbinary people, and intersex people who are at risk of exposure to HIV to have access to PEP. We also recommend removing the word "receptive", so the criteria include people who have insertive vaginal sex with known HIV positive partners or partners with unknown HIV status from either a high HIV prevalence country or high risk group (e.g. cisgender men, transgender women or non-binary people who have insertive vaginal sex with transgender men who have sex with other men). These changes help to ensure that transgender and non-binary people at risk of HIV acquisition have equitable access to PEP.

However, ensuring equitable access would only be the case if the current "Notes" section is removed. Currently, the notes specify that "unprotected receptive vaginal sex" refers only to intercourse between an HIV-positive male and an HIV-negative female. This clarifying note makes harmful and reductive heteronormative and cisnormative assumptions about the sexualities and genders of people based on the kind of sex being addressed. Not all people who have receptive vaginal sex are female and not all people who have insertive vaginal sex are male. The consequence of this "Notes" section is the discriminatory exclusion of transgender, non-binary, and intersex people from access to PEP. The notes are not necessary to clarify what is meant by "unprotected receptive vaginal sex" and may introduce ambiguity for a prescriber working with transgender, non-binary and intersex people around their eligibility for accessing PEP. Therefore, we insist on the removal of this notes section.

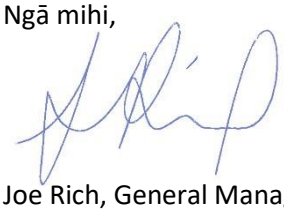
Summary

We strongly support the direction of PHARMAC's proposed changes to PrEP and PEP eligibility criteria. These changes help remove barriers to access which will help increase uptake, and ultimately help Aotearoa successfully end local HIV transmissions. We are in support of most changes to PrEP criteria. However, we have two key recommendations outlined in detail above. The first is the inclusion of a criterion ensuring clinicians' familiarity and use of local clinical guidance, with specific reference to the NZ Commentary to ASHM guidance. Our second recommendation is a change from requiring patients to be of no risk of seroconversion to requiring patients to have been assessed for risk of seroconversion.

We are also in favour of the widening of prescribers and eligibility criteria for PEP. However, we recommend replacing criteria 2.1 and 2.2 with one criterion that includes patients who have had anal or vaginal intercourse with someone from a high HIV prevalence country or risk group whose HIV status is unknown or a person living with HIV with unknown or detectable viral load. We also recommend removing the "Notes" section to ensure the criteria do not discriminate against transgender, non-binary, and intersex people.

Thank you for the opportunity to feedback on PHARMAC's proposed changes to these criteria. Please do not hesitate to contact the NZAF Policy and Science Manager Dr Jacek Kolodziej at 9 300 6952 or jacek.kolodziej@nzaf.org.nz should you require any clarification on the points made.

Ngā mihi,



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References:

1. Bavinton BR, Grulich AE. HIV pre-exposure prophylaxis: scaling up for impact now and in the future. The Lancet Public Health. 2021;6(7):e528-e33.
2. General Assembly United Nations, editor Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030. Seventy-fifth session 2021 9 June 2021.
3. Scott N, Stoové M, Kelly SL, Wilson DP, Hellard ME. Achieving 90-90-90 Human Immunodeficiency Virus (HIV) Targets Will Not Be Enough to Achieve the HIV Incidence Reduction Target in Australia. Clinical Infectious Diseases. 2018;66(7):1019-23.
4. Ludlam A, Saxton P, Dickson NP, Hughes AJ. General practitioner awareness of sexual orientation among a community and internet sample of gay and bisexual men in New Zealand. Journal of Primary Health Care. 2015;7(3):204-12.
5. Adams J, Neville S. Exploring talk about sexuality and living gay social lives among Chinese and South Asian gay and bisexual men in Auckland, New Zealand. Ethnicity and Health. 2020;25(4):508-24.
6. McGill CM, Collins JC. Creating Fugitive Knowledge Through Disorienting Dilemmas: The Issue of Bottom Identity Development. New Horizons in Adult Education & Human Resource Development. 2015;27(1):29-40.
7. Australasian Society of HIV Viral Hepatitis and Sexual Health Medicine. PrEP Guidelines Update for New Zealand. Prevent HIV by Prescribing PrEP. Auckland; 2021.
8. Better Practice. HIV Pre-Exposure Prophylaxis (PrEP): a how-to guide 2020 [updated 1 March 2020. Available from: https://bpac.org.nz/2019/prep.aspx.
9. Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine, New Zealand AIDS Foundation. Prescribing HIV Pre-Exposure Prophylaxis (PrEP) in New Zealand 2021 [Available from: https://www.nzaf.org.nz/media/2884/ashm_prep_tool_nzaf_update_04.pdf.
10. Auckland Region Community Health Pathways. Pre-exposure Prophylaxis for HIV (PrEP) n.d. [Available from: https://aucklandregion.communityhealthpathways.org/525496.htm.
11. Smith AKJ, Haire B, Newman CE, Holt M. Challenges of providing HIV pre-exposure prophylaxis across Australian clinics: qualitative insights of clinicians. Sexual health. 2021.
12. Hoffman S, Guidry JA, Collier KL, Mantell JE, Boccher-Lattimore D, Kaighobadi F, et al. A Clinical Home for Preexposure Prophylaxis. Journal of the International Association of Providers of AIDS Care (JIAPAC). 2016;15(1):59-65.
13. Anti-Infective Subcommittee of PTAC, editor Record of the Anti-Infective Subcommittee of PTAC meeting2019 10 May 2019; PHARMAC.
14. Gray RT, Wilson DP, Guy RJ, Stoové M, Hellard ME, Prestage GP, et al. Undiagnosed HIV infections among gay and bisexual men increasingly contribute to new infections in Australia. Journal of the International AIDS Society. 2018;21(4):e25104.
15. Li Z, Purcell DW, Sansom SL, Hayes D, Hall HI. Vital Signs: HIV Transmission Along the Continuum of Care - United States, 2016. MMWR Morb Mortal Wkly Rep. 2019;68(11):267-72.
16. Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine. Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV, Australian National Guidelines (Second Edition) n.d. [Available from: http://www.pep.guidelines.org.au/.