28 May 2025

Tēnā koe Chair, Alison Cossar, and members of the Medicines Classification Committee,

Tenofovir disoproxil and emtricitabine – proposed classification change to widen access to HIV prophylaxis medication (PrEP) in New Zealand

Thank you for considering the reclassification of tenofovir disoproxil and emtricitabine (TDF) for prevention of HIV at the 73rd MCC meeting held on 26 February 2025. We appreciate the Committee's careful consideration, feedback, and acknowledgement of the proposal's potential to improve access to HIV Pre-Exposure Prophylaxis (PrEP).

We are very grateful to the many people with whom we have consulted following receipt of the meeting minutes. Our response and the updated pathways have been written after input into the model from the Pharmaceutical Society of New Zealand, Te Whatu Ora | Health New Zealand stakeholders, sexual health clinicians, a community laboratory pathologist, GPs involved in PrEP supply, a pharmacist who has designed and researched many new pharmacy service initiatives, and pharmacy management software providers.

We appreciate the following comment in the MCC's minutes:

> *The MCC agreed that the proposal would widen access to HIV prophylaxis medication in New Zealand and could improve uptake by those not enrolled with a GP. The MCC agreed that the proposal has the potential to improve access and continuity of care for this group of people.*

Since our initial application to reclassify HIV PrEP, the latest HIV and AIDS epidemiology figures have been released from the University of Otago's HIV Epidemiology Group. In 2024, Aotearoa New Zealand witnessed the highest level of AIDS diagnoses in over a decade, as 28 people were diagnosed with AIDS. For 20 people, these AIDS diagnoses occurred within 3 months of their HIV diagnoses, suggesting they were diagnosed with HIV late. There were also inequities in relation to HIV diagnoses that are of concern: While only 8 European gay, bisexual or other men who have sex with men (MSM) were diagnosed with HIV in Aotearoa New Zealand, there were 16 Māori MSM and 6 Pacific MSM (1). Time is critical to improve access to prevention and eliminate HIV in Aotearoa New Zealand.

We have found considerable support for ensuring people not enrolled with general practice and not currently using the health system in Aotearoa New Zealand are looked after in this model. For example, one GP stated in an email to us:

> *"… improving access to people who are unenrolled is a critical success factor for this proposal. These are people who would have NO access if not for this initiative. These are the people who will avoidably seroconvert in the next 1-2 years if MedSafe don't act. Assuming the status quo is the safest option is not a fair starting point…. the proposed alternative to remain as status quo is NO ACCESS for this minority (no HIV, renal, STI screening or PrEP)."*

A pathologist working in lab testing explained that self-testing was increasingly seen as essential to reach certain groups of society and discussed the safeguards they have in place for this.

Thus, we have found a way to ensure we benefit this small but important group of non-enrolled patients while addressing the Committee's concern about self-requested tests. We have worked hard with stakeholders to redesign the model to protect an important minority and our community from HIV and encourage appropriate testing and follow-up with a backstop.

Additionally, we welcome the recent announcement that 12-month prescriptions may become available for certain medications. However, the best practice guidelines for PrEP supply in Aotearoa are unlikely to align with a 12-month supply due to the requirement for quarterly STI testing. Therefore, reclassification of this medication remains necessary to expand access.

This letter further develops our initial proposal. The three areas raised in your letter were:

1. Management of unenrolled patients and the associated flow of information
2. Pharmacy management systems
3. Self-ordering of lab tests by patients

These three points need to be considered in unison as they are related.

Pharmacist protocol changes to encourage engagement with primary care

The initiation pathway (see Appendix 1) has been revised to promote a collaborative care model as the primary access route. This aligns with the approach used for allopurinol, which received a positive recommendation from the MCC at its last meeting. We expect that most clients seeking PrEP from a pharmacist will be enrolled with a GP or under the care of a sexual health clinic (SHC). Collaborative models are likely to be the most common access route, as they are quick, flexible, and generally the most affordable option for those eligible for publicly funded healthcare in Aotearoa New Zealand. In these cases, clients typically have their blood tests arranged through a GP, telehealth provider, or SHC.

However, to support those who are unenrolled or unwilling to discuss PrEP with their GP, pharmacists will also be able to supply PrEP—provided the client meets the established criteria for supply. When a person requests PrEP, the pharmacist will recommend seeing an authorised prescriber. If that is not possible, they will facilitate self-requested testing via a community laboratory (e.g. Awanui, the provider of lab tests in much of Aotearoa). Note: The pharmacist is not the ordering party, and the client will be informed that results will be sent directly to them by email/phone. For these people, the pharmacist will be prompted to suggest finding a GP, SHC or telehealth provider for a regular check-up or when they need medical care, e.g., if they have a positive STI test. Burnett Foundation will develop a brief information sheet, with input from GPs and SHCs, to help guide this.

We have maintained the ability for self-requested test results to be used to initiate PrEP, as, for a small portion of users, it represents the only available access point, and feedback from consultation was clear that we need to aid this access to prevent new HIV infections.

When laboratory investigations are performed, pharmacists will act as a vital backstop. Suppose a person presents with a positive result (self-requested or through their GP or SHC). In that case, the pharmacist will be trained to ensure the person understands and reiterates the message to seek care delivered by the pathologist or requesting party. Pharmacists work collaboratively within the primary healthcare system and commonly refer people to general practice. Studies support that pharmacists have taken their roles seriously with these reclassifications (2-6).

New Zealand's pharmacists are highly trained and provide clinical oversight for prescription and non-prescription medications requiring laboratory monitoring. Pharmacists have demonstrated the clinical acumen necessary to extend their scope and regularly review renal function results and calculate creatinine clearance, including recent examples of clozapine, allopurinol, sildenafil, and ritonavir/nirmatrelvir (Paxlovid). They are familiar with recognising contraindications, assessing safety, and referring patients appropriately.

The need for access pathway improvements

PrEP has been available since 2017 and publicly funded since 2018, but during this time, many eligible individuals have not successfully accessed this medication. Health promotion of PrEP is high, and the population of MSM well understands the benefits (7). If we accept that those not currently on PrEP are 1) at a high risk of acquiring and spreading HIV and other STIs, and 2) not accessing any primary care, then perpetuating the status quo will lead to worse health outcomes overall – for these people as individuals, for other MSM, and HIV infection rates in NZ.

Pharmacy initiation of PrEP will trigger testing for these non-engaged clients, not just for HIV but also STIs, renal impairment, liver dysfunction, and Hepatitis B and C. Underlying health conditions will occur in this population, and so too will HIV and STI transmissions. With the planned safeguards in place, self-requested testing will facilitate access to PrEP and also diagnose some individuals with HIV or STIs and then engage them with treatment.

The unenrolled people seeking this prevention tool, while a small group, are vital to reach Aotearoa New Zealand's goal of local elimination of HIV. These will be people here from overseas who are newly migrated, unfamiliar or unengaged with our health system. These people may be moving around the country, unhoused or struggling with stigma and internalised homophobia. To eliminate local transmission of HIV, we must provide access to all clients who need it. The need for strong clinical oversight and referral pathways for clients with no GP is a valid consideration, and we have worked to mitigate any associated risks.

It's important not to underestimate or patronise this group—people seeking PrEP demonstrate proactive health behaviour. While a new STI diagnosis or navigating the referral process can be overwhelming for some MSM, particularly those unfamiliar with sexual health systems, pharmacist and pathology training ensures a strong and supportive referral network. These individuals are already engaged in prevention and testing and are likely to follow through with any additional care, including STI management. Furthermore, there are safeguards in place, as we have outlined throughout.

The Health and Disability Code of Conduct, Code of Health, and Disability Services Consumers' Rights gives people the right to make an informed choice and give informed consent, as outlined in Right 7: "Every consumer has the right to make an informed choice and give informed consent." This includes the right to receive clear, accurate information and to decide among available options for care. The Code also guarantees the right to safe and appropriate care, as stated in Right 4: "Every consumer has the right to have services provided with reasonable care and skill." This ensures that health services must be delivered in a manner that prioritises the consumer's safety, competence, and wellbeing. The proposed pharmacist model uses evidence-based guidelines, checklists, and clinical pathways, ensuring PrEP is provided to a safe, high standard. It also respects individual autonomy and self-determination, empowering and enabling consumers to have convenient and timely access, regardless of enrolment status, aiding uptake of this important service by those at risk by increasing access points. Furthermore, the pharmacist model connects people to health services (e.g. SHCs, GPs etc.), ensuring continuity of care.

Clinical oversight of the self-requested test pathways

We acknowledge the observations raised in the public submissions presented and the minutes from the 73rd meeting.

> *The MCC noted that for individuals not enrolled with a GP, it is unclear who is responsible for ordering blood tests and managing these results, as this would typically be the person's GP. This introduces risk regarding the access, interpretation and responsibility associated with blood tests from individuals not enrolled with a GP. The MCC discussed the management of abnormal lab results, and agreed that the proposal to have laboratory pathologists inform patients of their results and refer them to a GP would be difficult to implement and manage. The MCC agreed that this approach presents a risk of missing patients who have tested positive for HIV, creating risks to patients and their sexual partners.*

We also understand the MCC's perspective regarding patient-initiated laboratory testing without clinical oversight. The meeting minutes noted:

> *The MCC discussed that these issues may be exacerbated if patients were able to order their own lab tests. This could worsen access issues due to financial cost, particularly given the frequency of testing. Self-ordering of lab tests also introduces a risk of self-interpretation of these tests. The MCC agreed that self-ordering of laboratory tests should not be encouraged.*

We thank the MCC for these comments and have consulted widely on the clinical risks and costs associated with this service.

We would like the Committee to note that Awanui Labs is strengthening the self-request pathway via a contractual arrangement with DoctorsOnline. They are adding a telehealth clinician who works alongside the pathologists and laboratory to manage adverse lab results from self-requested tests. This partner would take clinical responsibility and ownership for following up on abnormal results triggered at specific thresholds**.** We have discussed this with the laboratory, and going forward, abnormal test results relating to PrEP can be referred to DoctorsOnline for follow-up. This will help people with abnormal tests while maintaining the

benefits of pharmacist access and having the pharmacist as a backstop if PrEP is requested with abnormal results. Consultation with GPs and sexual health clinicians has been positive, particularly given the pharmacist (who may be known already to the client) is there as back-up should the person present at the pharmacy. This system leaves very little room for self-interpretation of highly abnormal results.

Additionally, individuals undertaking self-requested testing will be emailed their results, so even if they could not be contacted (e.g. change of phone or do not answer), they should still receive their results. The emailed results include wording about the need to seek care, how to do so, and a referral pathway. Should an unenrolled person go to a GP or SHC to get tested, their ability to be contacted with the test result would be no greater than with a self-requested test.

Cost barriers exist regardless of prescriber, especially for those not enrolled with a GP, without a Community Services Card or without funded healthcare in NZ. This proposal provides another access option for people who may already be navigating those barriers—and mitigates harm by ensuring people aren't excluded from prevention. In many cases, SHCs already offer free STI testing, and they remain a primary referral point for unenrolled individuals with STI symptoms or concerns. We are working with laboratories and funders to establish low-cost or publicly funded pathways, as for other public health interventions (e.g. cervical screening, HIV testing).

Current use of self-requested testing in sexual health

Burnett Foundation Aotearoa has worked alongside Awanui Labs since 2021 to offer self-requested sexual health testing. This programme provides a clear precedent of engagement with over 1,200 clients using this service annually. Currently, patients self-request STI testing online. The results are reported to an Awanui pathologist, and a response cascade is initiated that dictates how the result is distributed depending on its severity. In most cases, individuals are responsible for seeking treatment after being adequately informed. This is a "passive referral" where the client presents for care. However, people who self-request are naturally expected to wish to act on the results. As we noted above, PrEP reclassification would stimulate the use of a referral to a telehealth system with Awanui for people self-requesting a "PrEP test" that is highly abnormal, and we are working with other labs on their processes.

This will give three levels of control, providing considerable safety:

1. For highly abnormal results, the client receives a call from a clinician to discuss their results.
2. All clients also receive an email with the results, including action needed, e.g. instruction to see a doctor.
3. Should a client request PrEP from the pharmacy, the pharmacist would see the test results requiring referral and be trained to discuss them and help link the client to care.

It is important to note that a positive STI, Hepatitis or HIV test will receive free treatment at an STI clinic or with an HIV specialist, respectively. Treatment is free for these communicable conditions under the Health Act, regardless of immigration status. The pharmacist would have

referral details for accessing this treatment, too. Other tests, e.g. eGFR or liver function tests, would stimulate referral to a doctor, and again, the pharmacist would be trained in discussing the importance of this referral with the client and helping them to seek help.

We know that doctors sometimes find it challenging to reach people by telephone (telehealth or otherwise). Therefore, having the client's email and pharmacist backstop (should they present for PrEP) provides a belt, braces *and* elastic band approach, with very high safety. We reiterate that these people seeking PrEP are motivated to look after their health, and a reasonable person in this situation can be expected to follow the advice of the clinician and pharmacist.

There is a growing trend internationally to enable self-requesting of tests as it increases access and early identification of transmissible diseases. In 2024, the World Health Organization (WHO) stated:

> *"HIV self-testing is now recommended for initiation, re-initiation, and continuation of PrEP and PEP across a range of service delivery options. This is an important step to accelerate access to PrEP through a range of person-centred service delivery models and prevent new HIV infections."*

There is real value in making STI testing more widely accessible. Barriers to HIV and STI testing include geographic access, comfort discussing sensitive issues, limited appointment availability or convenience, perceived judgment from staff, and concern about being stigmatised (8). Therefore, in Aotearoa New Zealand, we continue to see missed and late diagnoses of HIV and STIs (1). Furthermore, there is high acceptability of self-testing, and significant literature demonstrating that MSM find it convenient, preferable, and a service they are willing to use or pay for (9, 10).

Enabling more self-testing and self-requesting of laboratory testing addresses many of these barriers. Enabling self-testing has had an impact on the uptake of testing broadly, getting our communities into regular testing cycles, and reaching underserved populations (11-13). Evidence also demonstrates strong rates of follow-up and continued engagement in care (12-14).

See Appendix 3 for Draft parameters for HIV PrEP testing referral to clinician by lab.

See Appendix 4 for a Draft diagram of the referral pathway and the process for how and when a pharmacist will refer individuals or when a clinician will contact an individual.

See Appendix 5 for copies of existing self-requested testing advertising and availability

Note: draft documents have been supplied. They have had input from GPs, sexual health and pharmacists, but will be finalised with sign-off by all groups before implementation.

Management of pharmacist checks and referrals

Standardised protocols and training will ensure pharmacists can distinguish routine from complex presentations, with pharmacist consultations guided by clear referral criteria.

The proposed framework for pharmacist supply of PrEP includes a risk management process built around standardised checklists, structured referral pathways, and mandated comprehensive pharmacist training. These have been proven to work well in Aotearoa New Zealand for medicines such as oseltamivir, trimethoprim and Anti-D provision, with pharmacists very supportive of these models (15, 16). Furthermore, the pharmacy audits review supply documents in the pharmacy, providing an additional assurance of appropriate supplies. *See Appendix 2 – Pharmacist Supply Checklist.*

Any risks or contraindications, such as positive HIV status, reduced renal function, or concurrent medications, will be readily identified using the clinical checklist and lab results. Pharmacists have similar experience with drugs like ritonavir and nirmatrelvir (Paxlovid). This approach ensures that PrEP is provided safely, responsibly, and in a way that supports continuity of care where possible, access for the unengaged community and access to wider health services. Written information will be provided to those unengaged with the health system, so they know their options for engaging when needed.

In some cases, a client will first present to the pharmacist without test results or previous use of PrEP. This will be an essential first step by a client in exploring PrEP options, and it is crucial that this is handled in an affirming manner. The pharmacist would usually direct these clients to a GP or SHC for blood tests and engagement with a prescriber. For those who do not want to information will be provided about self-request testing – as noted previously, it is far better for a person to do testing and use PrEP than to do neither and be at risk of acquiring and transmitting HIV and STIs.

Risks with PrEP are minimal and can be carefully managed. Renal adverse events are rare, usually mild and reversible (17). Pharmacists will receive training on referral for a clinically relevant drop in eGFR, and how to handle this. TDF/FTC has a well-established safety profile that aligns with criteria for non-prescription availability. It carries a low risk of overdose, has minimal potential for misuse or abuse, and the dosing regimen is simple and easy to follow. Individuals are well placed to determine whether they need HIV protection, particularly those who are already taking active steps to assess their risk and seek prevention options. PrEP is not a recreational drug; it has no intoxicating effects, and there is no significant market incentive to misuse or divert it. We do not expect people who are unenrolled with a GP will attempt to circumvent testing requirements to avoid costs, doing so would require a high level of knowledge and effort, and the pharmacist will look up previous supplies or PrEP lab tests in the person's name. Moreover, the systems in place—such as linked laboratory testing and eligibility checks—act as strong safeguards to prevent inappropriate use. The Burnett Foundation has negotiated reasonable rates for PrEP self-requested testing with the leading laboratory provider to reduce barriers to access for those having to pay for this testing.

Pharmacy Management Systems

We acknowledge the MCC's concerns about pharmacy management systems, particularly regarding pharmacists' responsibilities related to abnormal blood test results. However, in the current scenario, pharmacists neither order blood tests nor directly receive results. Their role is

limited to reviewing test results provided by clients and acting according to their professional training and the established supply checklist.

Pharmacy management systems such as Toniq, RxOne, and re:care support electronic documentation through a digital supply document that captures relevant laboratory data, pharmacist-entered notes, action instructions, and client details. Although this completed document remains with the pharmacy visited by the client, it can later be reviewed on-site by other pharmacists and auditors.

Dispensing PrEP follows standard procedures used for other medications, with records captured via dispensary software and integrated into the client's medical record through systems like TestSafe and Eclair unless the client opts out. Pharmacists already manage similar processes for medications requiring lab result review, such as clozapine, Paxlovid, and, more recently, allopurinol. We have consulted with pharmacy system providers to confirm effective integration of laboratory results, pharmacist checklists, and referral documentation, and all reviewed systems support digitising the “Pharmacist Supply Checklist” (Appendix 1), significantly enhancing safety and record-keeping.

When clients engage via a collaborative model, results will be stored either in regional repositories or within patient-accessible PMS platforms such as Indici or ManageMyHealth. Clients can share their results through GP-connected apps or, with consent, pharmacists may access results through authorised systems like TestSafe, HealthOne, or Conporto. The pharmacist will document the completion and provision methods of the required tests.

Upon dispensing PrEP, records will be entered into the Medicines Data Repository, with results or supply records emailed to the patient’s GP unless the client chooses otherwise, similar to oral contraceptive practices.

If pharmacists find clients ineligible for PrEP after completing the checklist, this determination is documented in the pharmacy system, and clients are referred to a GP or SHC as per the defined referral process.

The HIV and pharmacy sectors have demonstrated a commitment to collaboration, patient safety and pragmatic and innovative solutions. This proposal seeks to expand PrEP provision to select pharmacies and is consistent with the government’s HIV Action Plan 2023-2030. Specifically, the government has called to:

> *Investigate new models to increase access to PrEP and PEP delivery. This could include establishing models for nurse-led PrEP and PEP delivery (including nurse prescribers in primary health care services) and piloting new models for delivery, such as telehealth, community-led and delivered initiatives, and provision in pharmacies. Representatives from priority groups should be involved in the process.*

Throughout this process of carefully developing the model, with input from many stakeholders and experts, we have been mindful of the HIV Action Plan and maximising safety for the community. We must act safely yet promptly to achieve our HIV elimination goals.

We greatly appreciate the feedback from the MCC to help us develop this further and address any concerns, with more input from experts, and are very pleased to present the updated model with a very positive benefit-risk equation, and further information to the MCC for consideration at the next MCC meeting.

We are grateful to the MCC for your careful consideration,

Ngā mihi nui,
Brooke and Alistair
Burnett Foundation Aotearoa

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