HIV pre- and post-exposure prophylaxis: a guide for primary care

Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) is an oral combination tablet, taken either daily or around a planned potential HIV exposure event, that can greatly reduce the risk of new HIV infection as part of a prevention strategy. The same medicine can also be used for post-exposure prophylaxis (PEP) to reduce the chances of developing HIV following an unplanned high-risk exposure. Both PrEP and PEP are available fully funded with Special Authority approval for people at high risk of HIV infection.

KEY PRACTICE POINTS:

- Since 2021, there has been an increase each year in the rate of human immunodeficiency virus (HIV) cases in New Zealand; men who have sex with men (MSM) remain at higher risk of infection
- Condom use is an effective strategy to reduce HIV infection (and sexually transmitted infections; STIs). Therefore, if people choose not to use them other preventative measures need to be encouraged.
- In 2023, the New Zealand Sexual Health Society released updated PrEP and PEP guidelines (see update box below)

Pre-exposure prophylaxis (PrEP):

- HIV PrEP (tenofovir disoproxil with emtricitabine) is an oral combination medicine that substantially reduces the risk of HIV transmission, when taken as recommended
- Daily PrEP is the conventional regimen, consisting of one tablet, once daily for as long as a person has an elevated risk of HIV infection
- An alternative protocol is event-driven PrEP, where dosing is based around a planned potential HIV exposure (sexual activity), and stopped after the exposure period has concluded; this protocol is not suitable for everyone (see main text for details)
- PrEP is funded with Special Authority approval for:
  - HIV-negative males, transgender or non-binary people who have sex with males and have multiple risk factors for HIV infection
  - HIV-negative people with partners who have a detectable HIV viral load
  - HIV-negative people who inject drugs and may be at higher risk of HIV due to sharing of equipment
- Prior to initiating PrEP, investigations should include HIV serology, screening for STIs, hepatitis B and C, renal and hepatic function and a pregnancy test, if applicable
- Ongoing monitoring for patients receiving either daily or event-driven PrEP should occur every three months, including assessment of medicine adherence, adverse effects, and testing for HIV, STIs and other investigations as required
- Continuing to promote the consistent and correct use of condoms to prevent HIV and other STIs remains an important aspect of management

Post-exposure prophylaxis (PEP):

- Oral tenofovir disoproxil with emtricitabine, with or without dolutegravir, can also be prescribed as HIV PEP for patients who present within 72 hours of a potential HIV exposure (non-occupational)
  - N.B. Only named specialists (e.g. sexual health or infectious diseases physician) can prescribe PEP for occupational exposures, e.g. needlestick injuries.
- The decision to prescribe PEP should be based on the patient's exposure history and risk factors for HIV transmission, as well as risk factors for the source, if known
- PEP is more effective the earlier it is taken after exposure; ideally within 24 hours, however, it can be initiated up to 72 hours later

PrEP and PEP – supporting and encouraging use:

- A reported barrier to PrEP for patients is not knowing how or where to access it and not feeling comfortable discussing their sexual health with a healthcare professional
- Providing open, safe and non-judgemental care reduces barriers for people who would benefit from HIV PrEP/PEP the most. This can be achieved by displaying/promoting services and resources relating to health issues for MSM, reminding the patient about doctor-patient confidentiality, explaining the purpose of questions before asking them and using inclusive language.

This is a revision of a previously published article: HIV Pre-Exposure Prophylaxis (PrEP): a how-to guide, April, 2019. What's new for this update:

- General article update based on new PrEP and PEP guidelines for Aotearoa New Zealand (2023), available from: **www.nzshs.org/guidelines/**
  - Summary flow charts with key information for prescribing PrEP and PEP are also available from: **www.nzshs.org/guidelines/**
- Updated funding and prescribing information for PrEP, including event-driven dosing
- New major section added on PEP for non-occupational HIV exposures
- Guidance added on promoting a safe and open space for MSM to discuss sexual health

HIV infection disproportionately affects men who have sex with men

Rates of human immunodeficiency virus (HIV) infection have generally been declining in New Zealand, since a peak in 2016.[1] In 2023, there were 97 newly diagnosed cases (see: "HIV in New Zealand: where are we at?").[1] HIV infections predominantly occur in men who have sex with men (MSM), who accounted for two-thirds of infections diagnosed locally in 2023.[1] Factors that contribute to the increased risk in this group include:[2, 3]

- **Type of sexual activity** – receptive anal intercourse has a higher risk of HIV infection than vaginal intercourse because the rectal mucous membrane separating semen from cells susceptible to infection is thinner and more vulnerable to damage
- **Higher rates of HIV** – the rate ratio of MSM in New Zealand who acquire HIV is much higher than the general population: gay and bisexual men have been reported as being up to 348 times more likely to have HIV than people who identify as heterosexual[4]
- **Small MSM population** – the sexual networks of MSM are closer and as they are a minority within the general population, the transmission of STIs between sexual contacts is more likely

Condoms remain an effective method of reducing HIV transmission

When used correctly and consistently, condoms substantially reduce HIV transmission via anal intercourse.[5, 6] Overall condom use by MSM in New Zealand has increased since the HIV epidemic began, but data suggest that rates among casual MSM partners is declining.[3, 7] HIV PrEP provides another strategy to reduce the risk of HIV transmission, particularly for people who are not using condoms consistently.

Part 1: HIV pre-exposure prophylaxis (PrEP)

HIV PrEP is fully funded for key populations

In 2018, New Zealand became one of the first countries in the world to fully fund oral tenofovir disoproxil with emtricitabine for HIV infection prophylaxis (with Special Authority approval).[8] Increased awareness among both prescribers and patients, and relaxing of Special Authority criteria, have since led to improved community uptake, however, some people who may benefit from PrEP are still missing out. The ongoing challenge for primary care is to ensure that the people most at risk of HIV infection can easily and safely access either daily or event-driven PrEP.

PrEP is a combination oral tablet containing 245 mg tenofovir disoproxil with 200 mg emtricitabine.[9] Tenofovir disoproxil and emtricitabine are reverse transcriptase inhibitors that prevent a key step in the HIV replication cycle.[5] It can also be used for post-exposure prophylaxis (unapproved indication) within 72 hours of a potential exposure to HIV (see: "Part 2: HIV post-exposure prophylaxis [PEP]").[10] Furthermore, tenofovir disoproxil with emtricitabine may be prescribed as part of a treatment regimen for people with HIV to reduce viral load but cannot eliminate infection once established.[5, 11]

Best practice tip: When prescribing PrEP or PEP, ensure the correct combination product is specified using the generic name and the correct strength to avoid errors: tenofovir disoproxil 245 mg + emtricitabine 200 mg. N.B. Tenofovir disoproxil is available as a single medicine in New Zealand but evidence supporting its use as PrEP monotherapy is not available. This preparation should not be prescribed for this purpose.[9, 12]

Who should be offered PrEP

People are eligible for funded PrEP if they are considered at higher risk of HIV exposure and are confirmed to be HIV-negative.[10] Suitability criteria have been developed for MSM (or transgender* and non-binary† people who share networks with MSM), heterosexual people and people who inject drugs, to aid prescribers when determining if a person is at higher risk of HIV exposure (Table 1). Given the commitment daily PrEP requires (e.g. adherence, regular monitoring), an early discussion with patients is beneficial in determining if this treatment is right for them (also see event-driven dosing below).

Special Authority initial applications (and renewals) for funded daily and event-driven PrEP can be submitted by any relevant practitioner, including general practitioners and nurse practitioners.[13] Special Authority approval is valid for 24 months and must be renewed every 24 months thereafter.[13] In 2018, it was estimated that 5,800 people in New Zealand were eligible for PrEP, which included 18% of all sexually active

MSM;[14] these numbers have likely increased with the relaxing of Special Authority eligibility criteria in July, 2022.

* A person whose gender identity does not correspond with their sex assigned at birth

† A general term for the gender of a person who does not identify as exclusively male or female

The Special Authority application form for PrEP can be found **here**

People who are at higher risk of HIV exposure but not eligible for publicly funded healthcare in New Zealand, e.g. non-New Zealand residents, overseas travellers, should still be assessed to establish whether PrEP is likely to be beneficial.[10] Self-funding (approximately NZ$30 per month) may be an option if PrEP is determined to be appropriate for the patient, however, additional costs for consultations and required testing also need to be factored in, and together this could be a barrier to use.[10]

Burnett Foundation Aotearoa may be able to offer support to some patients if the cost of PrEP is a barrier to access. Further information is available from: **www.burnettfoundation.org.nz/articles/news/free-prep-for-low-income-nzers-and-international-students/**

Testing before initiating PrEP

Patients should be tested for HIV as part of the initial evaluation for PrEP; a negative result is required for Special Authority approval.[10] A person who has been infected with HIV may not test positive for up to 45 days following transmission, i.e. the window period.[10] Patients who report a recent high-risk exposure within this period, and then initially test negative for HIV should undergo a follow-up HIV blood test approximately one month after initiating PrEP.[10] N.B. PEP may be appropriate in cases where the high-risk exposure occurred within 72 hours (see: "Part 2: HIV post-exposure prophylaxis [PEP] ").[10]

HIV in New Zealand: where are we at?

In 2023, there were 97 people diagnosed with HIV in New Zealand; an increase compared to 2021 (67 people) and 2022 (76 people).[1] This increase is potentially a result of the removal of social and border restrictions relating to the COVID-19 pandemic. Locally diagnosed infections are still less than pre-pandemic levels, but it is uncertain whether HIV infections will continue to increase, stabilise or decline in the next few years. New Zealand data from 2023 show that:[1]

- New HIV infections were predominantly diagnosed in MSM (67%)
  - Of the 65 locally diagnosed MSM with HIV infection, approximately 69% resided in the North Island, with the majority living in the greater Auckland region
  - There was a disproportionate ethnic representation compared to the general population: 29% European, 23% Asian, 20% Māori, 15% Pacific Peoples and 12% Latin American or African
  - The age at diagnosis for MSM who acquired HIV ranged from 19 to 75 years
- There was a significant increase in the number of HIV notifications in people first diagnosed overseas from 55 people in 2022 to 123 in 2023. However, more than 90% of these people had an undetectable viral load (suggesting they were taking antiretroviral medicines), and therefore pose no risk of sexually transmitting HIV.
- The number of locally diagnosed HIV infections in heterosexual people remained consistent with previous years (seven males and ten females)
- It is rare for people who inject drugs to acquire HIV infection (there were two people with locally acquired HIV in whom this was reported as a potential cause). This low rate is likely due to the early and successful implementation of needle exchange programmes in New Zealand.
- The total number of people living with HIV is unknown, however, as of June, 2023, approximately 3,300 people were receiving funded antiretroviral treatment

For further information regarding HIV and AIDS notification data in New Zealand, see: **aidsepidashboard.otago.ac.nz**

AIDS is decreasing in New Zealand

HIV exists on a spectrum that begins with acute infection. If left untreated, chronic HIV infection can progress to acquired immunodeficiency syndrome (AIDS), which has a high mortality rate due to opportunistic infections and HIV-associated cancers.[5] In New Zealand, AIDS-associated deaths peaked at approximately 70 per year in the late 1980s and early 1990s, and have since declined.[1] Data from 2023 show that 14 people were diagnosed with an **AIDS-defining illness** in New Zealand, 11 of whom were identified within three months of their HIV diagnosis, suggesting they had been living with undiagnosed HIV for a substantial period of time and had not received antiretroviral treatment.[1] Increasing the uptake of regular HIV testing is crucial to avoid diagnosis at the stage of AIDS.

Table 1. Suitability criteria for determining people who are at higher risk of HIV exposure. *Adapted from NZSHS PrEP and PEP guidelines (2023).*[10]

HIV risk factors for MSM (or transgender or non-binary people who share networks with MSM)

- ☐ Condomless anal or vaginal intercourse with a regular HIV-positive partner who is either not receiving treatment, or who is receiving treatment but has a detectable HIV viral load > 200 copies/mL
- ☐ Condomless anal or vaginal intercourse with any casual or non-exclusive MSM partner
- ☐ One or more episode of rectal gonorrhoea, rectal chlamydia or infectious syphilis
- ☐ One or more episode of anal intercourse where a condom slipped off or broke, where the HIV serostatus of the partner was not known, or where the partner was HIV-positive and not receiving treatment or had a detectable viral load > 200 copies/mL
- ☐ When a person presents with concerns of deteriorating mental health and there is a possibility of increased HIV acquisition risk behaviour in this setting
- ☐ When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use (especially methamphetamine*) and has concerns about their HIV acquisition behaviour in this setting

* The use of methamphetamine is known to increase the likelihood of high-risk behaviour, e.g. anal intercourse without condoms, group sex, multiple sex partners and injecting drugs

Patients in whom any of these risk factors for HIV exposure apply to either in the previous three months and/or may apply to in the next three months should be offered PrEP.

PrEP could also be considered in situations where a patient is in a relationship with a person with HIV who is receiving antiretroviral treatment (and is virologically supressed) but is experiencing undue suffering and anxiety regarding HIV transmission ***or*** *anxiety regarding HIV infection prevents the patient from regular HIV testing or engaging in any form of anal intercourse.*

HIV risk factors for heterosexual people

- ☐ At least one episode of condomless intercourse (insertive or receptive) with a regular HIV-positive partner who is either not receiving treatment, or who is receiving treatment with a detectable viral load > 200 copies/mL
- ☐ Condomless intercourse with any casual MSM partner of unknown HIV status
- ☐ Overseas travel to a high HIV prevalence country, and condomless intercourse with partners of unknown HIV status

Patients in whom any of these risk factors for HIV exposure apply to either in the previous three months and/or may apply to in the next three months should be offered PrEP.

PrEP could also be considered in situations where a patient is in a relationship with a person with HIV who is receiving antiretroviral treatment (and is virologically supressed) but is experiencing undue suffering and anxiety regarding HIV transmission.

HIV risk factors for people who inject drugs

- ☐ Shared injecting equipment with a HIV-positive person or with MSM of unknown HIV status

Patients in whom this risk factor for HIV exposure applies to either in the previous three months and/or may apply to in the next three months should be offered PrEP. N.B. In some cases, people who inject drugs may also be at elevated risk for HIV infection through sexual behaviour.

Additional recommended tests before initiating PrEP include (Table 2):[10]

- Blood tests for syphilis and hepatitis A*, B and C (unless known immunity to hepatitis A or B†)
- Multi-site nucleic acid amplification test (NAAT) for chlamydia and gonorrhoea (first-pass urine for males, and rectal, urethral, vaginal and pharyngeal swabs as indicated)
- Estimated glomerular filtration rate (eGFR)**, creatinine, protein:creatinine ratio‡
- Liver function tests
- Pregnancy testing in people of childbearing potential

* Testing for hepatitis A is not funded for this indication in New Zealand and is not a requirement when initiating PrEP, however, clinicians should consider offering it to patients at higher risk of infection, e.g. MSM or people who inject drugs[10]

† Patients who do not have immunity to hepatitis A or B should be offered vaccination (however, neither hepatitis A nor B vaccination is funded in this situation)[10]

** Creatinine clearance (CrCl) using the Cockcroft–Gault equation is considered the optimal method for assessing renal function but this may not always be practical in primary care.[10] A creatinine clearance calculator is available from: **nzf.org.nz/nzf/resource/Creatinine%20Clearance%20Calculator.htm**

‡ The use of protein:creatinine ratio is recommended over albumin:creatinine ratio as albuminuria predominantly indicates glomerular dysfunction, however, tenofovir-associated renal impairment generally involves proximal tubular dysfunction (indicated by low molecular weight proteinuria), while the glomerular filtration barrier is often unaffected[15]

Prescribing considerations based on patient history or baseline test results

Do not initiate PrEP in a patient who returns an indeterminate HIV test result during preliminary testing.[10] Assess for symptoms and signs of acute HIV infection and discuss with an infectious diseases or sexual health physician.[10] PrEP should only be commenced once HIV infection has been ruled out.[10]

Chronic hepatitis is not a barrier to taking PrEP, however, it is important to establish hepatitis status and liver function prior to commencing prophylaxis as there may be an increased risk of hepatic adverse effects; discuss with a hepatologist or infectious diseases physician.[10]

Precaution for people with hepatitis B: tenofovir disoproxil and emtricitabine are both active against hepatitis B; withdrawal from PrEP can lead to reactivation of hepatitis B and hepatic injury, and possible development of hepatitis B resistance to tenofovir disoproxil with emtricitabine.[10] Patients with hepatitis B should only be offered daily PrEP (event-dosing is not suitable; see: "Which PrEP regimen is most suitable for my patient ?") and discuss the importance of adherence.[10]

Ongoing testing for hepatitis B is not necessary in patients who are immune unless there is an unexplained elevation in alanine aminotransferase (ALT).

Immunisation against both hepatitis A and B viruses is recommended for MSM and should be offered to patients who have not demonstrated immunity, however, vaccination for this group is not funded.[10] Immunisation against hepatitis B is also recommended for people who inject drugs and immunisation against hepatitis A should also be considered.[10]

People with a bacterial STI, e.g. chlamydia, gonorrhoea or syphilis, can take PrEP and this should not be a reason to delay initiation.[10] Advice should be given about condom use, STI symptoms and signs, along with initial and ongoing testing to detect STIs and prompt treatment if a STI is detected.[10]

PrEP is contraindicated in people with an eGFR < 60 mL/min/1.73 m^2, as clinical studies have not been conducted in this group and treatment with tenofovir disoproxil has occasionally been associated with nephrotoxicity.[10] Following initiation of PrEP, assess serum creatinine, eGFR and protein:creatinine ratio at three months and then at six monthly intervals thereafter.[10] More frequent monitoring of eGFR may be appropriate for patients who are at risk of renal disease, including those who:[10]

- Are aged over 40 years; studies have shown that the use of PrEP in this age group is associated with a more rapid decline in renal function
- Have an eGFR < 90 mL/min/1.73 m^2
- Are taking another nephrotoxic medicine long-term, e.g. NSAIDs
- Have relevant co-morbidities, e.g. hypertension, diabetes

Effective contraception should be provided to all people of child-bearing potential taking PrEP who do not wish to become pregnant.[10]

PrEP can be taken during pregnancy after balancing the risks and benefits; there is an increased risk of HIV infection during pregnancy, but lower neonate bone mineral density is a potential adverse effect of tenofovir disoproxil with emtricitabine.[10] Both tenofovir disoproxil and emtricitabine may be present in breast milk but are not expected to be harmful to the infant; monitor for adverse effects.[9]

PrEP can be prescribed two ways

Daily PrEP is the conventional regimen that involves taking one combination tablet of 245 mg tenofovir disoproxil with 200 mg emtricitabine once daily, without interruption, until the person is no longer considered to be at higher risk of HIV infection, i.e. their circumstances and hence their risk assessment changes (Figure 1). The efficacy of daily PrEP is directly related to adherence; a pooled analysis of 72 studies involving over 17,000 participants taking oral tenofovir disoproxil with emtricitabine between 2011 and 2019 found only 101 new diagnoses of HIV infection in that period.[16] Most of these cases were attributed to low adherence, i.e. taking less than two doses per week.[16]

Guidelines state that tenofovir disoproxil with emtricitabine-based PrEP is most effective at reducing a person's risk of HIV infection after being taken for seven consecutive days. However, it is likely that concentrations of tenofovir disoproxil and emtricitabine reach sufficient levels for protection from HIV earlier in rectal tissues than in vaginal tissues.[10, 17] Therefore, recommendations about when protection is attained differ between patient groups:[10]

- **Cisgender* males and people assigned male at birth who are not taking oestrogen-based gender affirming hormone therapy** can start daily PrEP by taking two combination tablets of 245 mg tenofovir disoproxil with 200 mg emtricitabine between 2 – 24

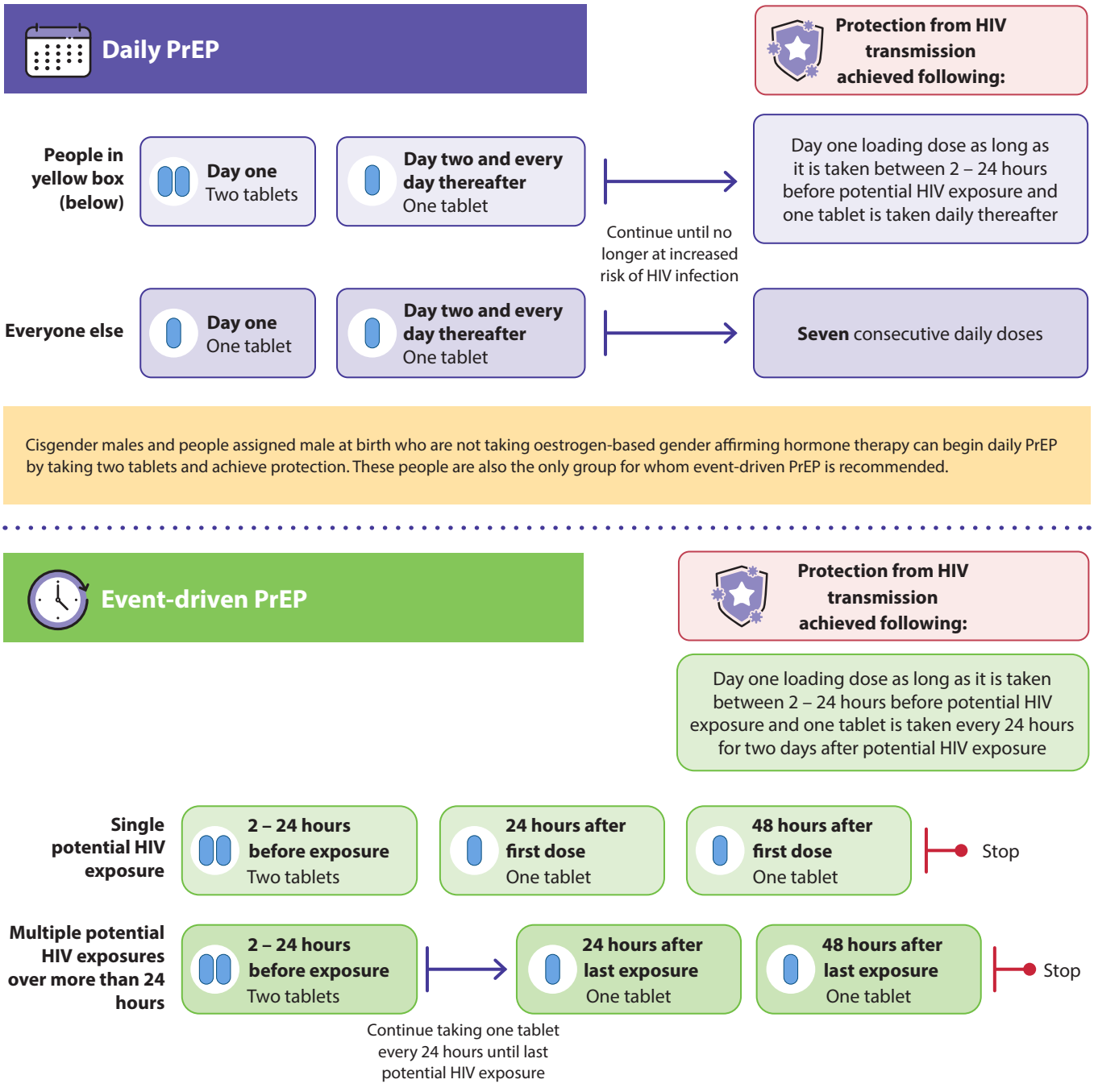

Figure 1. Summary of daily and event-driven PrEP initiation.[10]

hours before a potential HIV exposure, i.e. on the first day, and then take one tablet every day thereafter

- **All other people** starting daily PrEP should take one combination tablet of 245 mg tenofovir disoproxil with 200 mg emtricitabine for at least **seven days** before a potential HIV exposure, and then continue taking one tablet every day thereafter

* Denotes a person whose gender identity matches their sex assigned at birth

Event-driven PrEP, or 2 – 1 – 1 PrEP, is an "as required" dosing regimen in which the patient takes (Figure 1):[10]

- Two combination tablets of 245 mg tenofovir disoproxil with 200 mg emtricitabine 2 – 24 hours before a potential HIV exposure, i.e. sexual activity
- One combination tablet 24 hours after the first dose
- Another combination tablet 48 hours after the first dose to complete the course

People who have multiple exposures over consecutive days should take the two-tablet loading dose 2 – 24 hours before the first exposure, and then one combination tablet every 24 hours until their last exposure. The course is then completed by taking one combination tablet at both 24 and 48 hours after their last HIV exposure.[10]

Which PrEP regimen is most suitable for my patient?

Daily PrEP is the most commonly prescribed regimen and is appropriate and recommended for all patients who are at higher risk of HIV infection (unless contraindicated, e.g. eGFR < 60 mL/min/1.73 m^2).[10] Event-driven PrEP is an alternative regimen for people in whom daily PrEP may not be practical or acceptable, e.g. they have sex infrequently or struggle with adherence, or they do not qualify for funded PrEP and cannot commit to the cost of daily dosing.[10] However, event-driven PrEP is only recommended for cisgender males and people assigned male at birth who are not taking oestrogen-based gender affirming hormone therapy.[10]

While there is limited evidence regarding the toxicity of event-driven PrEP compared to daily PrEP, the available data show no significant difference in serious adverse effects between the two regimens.[10] However, people who take event-driven PrEP may be more likely to experience gastrointestinal adverse effects, possibly due to starting and stopping the medicine often.[10]

N.B. PrEP is funded for use in either regimen if the person meets Special Authority criteria (see: "Who should be offered PrEP").

Event-driven PrEP should not be offered to people assigned female at birth or people taking oestrogen-based gender affirming hormone therapy.[10] There is insufficient evidence supporting event-driven PrEP in these groups and additionally, oestrogen potentially reduces circulating levels of active tenofovir disoproxil and emtricitabine metabolites.[10] Strict adherence to daily PrEP is required to maintain adequate tissue concentrations for protection from vaginal HIV infection, therefore event-driven PrEP may not provide adequate protection in people who engage in receptive vaginal intercourse.[10]

Event-driven PrEP is contraindicated in people with chronic hepatitis B due to the possibility of hepatitis flares after event-driven PrEP stops.[10]

PrEP can be prescribed to younger people "off-label"

Tenofovir disoproxil with emtricitabine is not approved for use in people aged under 18 years as HIV PrEP, however, it can be prescribed "off-label" following discussion with an infectious diseases or sexual health physician (and funded if the patient meets Special Authority criteria).[10] The decision to prescribe PrEP should take into consideration the risks, e.g. potential for impaired bone growth, and benefits, i.e. reduced risk of HIV infection. Informed consent should be obtained and recorded in the patient's notes.[10]

There have not been any studies on the efficacy of event-driven PrEP in adolescent MSM and adherence rates may be lower, therefore caution is advised when prescribing this regimen.[10] Consider more frequent monitoring to assess adherence and adverse effects.[10]

Encourage adherence to ensure ongoing protection

Before PrEP is prescribed, patient discussions should include:[10]

A clear explanation of how PrEP works and the importance of taking it as recommended to ensure protection from HIV transmission

Information about potential adverse effects, e.g. gastrointestinal disturbances, and reassurance that these usually resolve within one month of initiating PrEP (see: "PrEP adverse effects are generally mild and transient")

Advice about adherence such as setting a routine for dosing, e.g. in the morning with toothbrushing for daily dosing or setting alarms for event-driven dosing. Dosing at a consistent time each day is recommended, however, serum concentrations are unlikely to be affected by small variations, e.g. a few hours. Any barriers to adherence should be identified and addressed, e.g. illicit substance use or mental illness.

Table 2. Laboratory testing recommendations for initiation and follow-up of patients taking either daily or event-driven PrEP. *Adapted from NZSHS PrEP and PEP guidelines (2023).*[10]

Investigation	Baseline testing before PrEP	Testing one month following PrEP initiation	Testing three months following PrEP initiation	Ongoing testing every three months	Additional testing frequency
HIV serology	✓	✓ (if high-risk exposure within 45 days of initiating PrEP)	✓	✓	
Full STI screen (blood tests for HIV and syphilis and NAAT for chlamydia and gonorrhoea [first-pass urine, and rectal, urethral, vaginal and pharyngeal swabs as indicated])	✓		✓	✓	
Serum creatinine and eGFR	✓		✓		Every six months More frequent monitoring, e.g. every three months, may be appropriate if age > 40 years, eGFR < 90 mL/min/1.73 m^2, hypertension or diabetes or taking NSAIDs long-term
Urine protein:creatinine ratio	✓		✓		Every six months
Hepatitis A serology*	✓ (should be offered but is not funded)				
Hepatitis B serology†	✓				If vaccinated at baseline, confirm immune response one month after final dose If vaccination declined or not immune, test three months after initiating PrEP and every three months thereafter
Hepatitis C serology	✓				At least every 12 months More frequent monitoring indicated in people who inject drugs or MSM who engage in sexual practices that increase the risk of anal trauma
Liver function tests	✓				Ongoing liver function testing not routinely indicated but may be appropriate in patients with chronic hepatitis or symptoms of hepatic impairment, e.g. abdominal pain, jaundice, weight loss
Pregnancy test for people of child-bearing potential	✓	✓	✓	✓	

* Testing for hepatitis A is not funded for this indication in New Zealand and is not a requirement when initiating PrEP, however, clinicians should consider offering it to patients at higher risk of infection, e.g. MSM or people who inject drugs

† Ongoing testing for hepatitis B is not necessary for immune patients unless there is an unexplained elevation in alanine aminotransferase

What to do if a dose is missed; advise the patient they can start again when they remember and not to take a double dose the next day. Patients on daily dosing are unlikely to be protected if they have taken fewer than four doses within one week.

A caution that PrEP is recommended if the patient consistently reports taking fewer than four doses per week (see: "Withdrawing PrEP")*

* Switching the patient to event-driven PrEP may be appropriate in some situations

Patient information on HIV PrEP is available from: **www.burnettfoundation.org.nz/learn/staying-safe/prep/**

Patients taking PrEP require regular follow-up and monitoring

Initially prescribe a quantity of PrEP sufficient for 90 days for patients starting either daily or event-driven PrEP regimens.[10] All patients taking PrEP require a follow-up appointment after three months and then regular follow-up consultations every three months thereafter to assess for adverse effects and medicine adherence.[10] Recommended laboratory testing should occur within the two weeks prior to prescription renewal (Table 2). Patients prescribed event-driven PrEP should also undergo regular three-monthly follow-up, including clinical review and laboratory evaluation, even if they do not require another prescription.[10]

PrEP adverse effects are generally mild and transient

Gastrointestinal symptoms, e.g. nausea, vomiting, abdominal pain, flatulence, diarrhoea and headache, are the most frequently experienced adverse effects by people who start PrEP.[9, 10] These are most likely to be reported in the first month of treatment and are unlikely to persist past three months.[10]

The principal concerns for patients prescribed PrEP are acute kidney injury and hepatic impairment (there is an increased risk of hepatic adverse effects in patients with chronic hepatitis). Ensure patients know to seek medical attention if they have symptoms of concern outside of their scheduled follow-up appointments. Patients should be advised to seek immediate medical attention if they develop any symptoms of acute kidney injury, such as oliguria (decreased urinary output) or lower limb oedema.[10]

Monitoring for acute HIV infection (due to non-adherence to the regimen or pre-existing infection) is also important. Potential symptoms include fever, sore throat, fatigue, headache, rash, myalgia and lymphadenopathy.[10]

Bone density may be reduced slightly in people taking tenofovir disoproxil with emtricitabine.[10] Older patients or those with multiple risk factors for fractures, e.g. high alcohol consumption, smoking, low body mass index (BMI), should be advised about ways to reduce their risk.[10] Bone health can be maintained via reducing alcohol intake, smoking cessation, adequate dietary calcium intake, adequate exposure to sunlight to maintain vitamin D levels and regular weight-bearing exercises.[10]

Managing declining renal function

PrEP is contraindicated in patients with an eGFR < 60 mL/min/1.73 m^2.[10] However, continuation may be possible if renal function drops below this point, but only following discussion with a sexual health or infectious diseases physician with expertise in PrEP, or a nephrologist.[10] In some situations, event-driven PrEP may be a practical option for eligible patients with an eGFR close to the 60 mL/min/1.73 m^2 threshold.[10] N.B. eGFR can vary for many reasons, e.g. hydration status, muscle mass, recent change in diet, therefore, if testing indicates eGFR is < 60 mL/min/1.73 m^2 consider repeating the test to confirm the result before withdrawing PrEP.[10]

Interactions with other medicines and nephrotoxicity

Tenofovir disoproxil and emtricitabine predominantly undergo renal excretion; concurrent use of medicines that are nephrotoxic or compete for active tubular secretion may cause serum levels to increase, e.g. valaciclovir, aminoglycosides or long-term NSAIDs.[10] Nephrotoxicity is rare in patients taking PrEP, although proximal tubular dysfunction can occur, e.g. Fanconi syndrome, hence monitoring of renal function is recommended (Table 2).[10]

Information about potential interactions between PrEP and other medicines is available on the New Zealand Formulary interactions checker: **www.nzf.org.nz/nzf_1**. An interactions checker specific to HIV medicines is also available from the University of Liverpool: **www.hiv-druginteractions.org/checker**.

Renewing funded PrEP

To renew Special Authority approval for funded PrEP (required every 24 months) the patient must still meet the same initial criteria:[13]

- Confirmed HIV-negative in the past 14 days (no symptoms and signs of acute infection); AND
- Still considered at high risk of HIV exposure and the prescriber believes the use of PrEP is appropriate

Best practice tip: While previous criteria for renewal of Special Authority, including regular STI and renal function testing and patient education, are no longer required to be met, they are still best practice care and should occur regularly as part of ongoing follow-up and monitoring (see: "Patients taking PrEP require regular follow-up and monitoring").

Withdrawing PrEP

Long-term use of PrEP may not be necessary for some patients, e.g. if they start consistently using condoms or enter a mutually monogamous relationship with a partner who is HIV-negative.

The duration that PrEP should be continued following the last potential HIV exposure differs between patients:[10]

- **Cisgender males and people assigned male at birth who are not taking oestrogen-based gender affirming hormone therapy** who are taking daily or event-driven PrEP should continue taking it for **two days** after their last potential HIV exposure, i.e. one dose 24 hours after the last exposure and another dose 48 hours afterwards
- **All other patients** should continue taking PrEP for **seven days** after their last potential HIV exposure

Record the patient's HIV status, reasons for discontinuing PrEP, adherence while being treated and risk-taking behaviour.[10] Funded PrEP can be reinitiated if the patient's risk of HIV infection increases in the future and they continue to meet Special Authority criteria.[10]

Any patient with chronic hepatitis B infection should be discussed with a hepatologist or infectious diseases physician with expertise in managing hepatitis B before withdrawing from PrEP, due to the risk of hepatitis reactivation.[10]

Continue to encourage the consistent use of condoms for all sexual contact

Ensure patients understand that PrEP only protects against infection with HIV, and only if taken as prescribed.[10] Encouraging the consistent and correct use of condoms to prevent HIV, other STIs and unwanted pregnancy is essential.[10] Condom use should be discussed when PrEP is started and at follow-up appointments.[10]

Specific topics to discuss include:[10]

- Any barriers to consistent condom use
- Reducing any illicit substance use; people with substance use disorder are at higher risk of STIs[18]
- Identifying other steps that patients can take to reduce their STI risk, e.g. vaccination against human papillomavirus (HPV), hepatitis A and B
- Acknowledging efforts by the patient to reduce their risk and to reinforce these successes

Part 2: HIV post-exposure prophylaxis (PEP)

HIV PEP can now be prescribed in primary care

Tenofovir disoproxil with emtricitabine is also a first-line emergency treatment for any patient following a potential HIV exposure, e.g. unprotected consensual sex, sexual assault or other high-risk sexual exposure.[10] Post-exposure prophylaxis (PEP) is a 28-day course of daily tenofovir disoproxil with emtricitabine, with or without an additional antiretroviral (dolutegravir). It is recommended to start PEP as soon as possible following the potential exposure, ideally within 24 hours, however, it can be initiated up to 72 hours later (after which it is no longer considered effective).[10] PEP is not currently an approved indication for tenofovir disoproxil with emtricitabine or dolutegravir therefore it must be prescribed "off-label".

PEP is prescribed with Special Authority approval

A 28-day course of daily tenofovir disoproxil with emtricitabine, with or without dolutegravir, may be prescribed fully funded with Special Authority approval for patients who meet the criteria following a non-occupational exposure.[13] Since July, 2022, Special Authority applications for funded PEP in patients with non-occupational exposure to HIV can be submitted by any relevant practitioner, including general practitioners and nurse practitioners.[13]

A list of pharmacies that may stock PrEP and PEP is available from: **www.healthpoint.co.nz/pharmacy/?serviceArea=im%3A1550889** (patients are advised to contact the pharmacy first to confirm stock availability). N.B. Tenofovir disoproxil with emtricitabine and dolutegravir are not available on Practitioner Supply Order (PSO).

Special Authority criteria for PEP requires **both**:[13]

1) Treatment course is initiated within 72 hours of exposure; and
2) Any of the following:
   i. Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV-positive person with an unknown or detectable viral load > 200 copies/mL; or
   ii. Patient has shared intravenous injecting equipment with a known HIV-positive person; or
   iii. Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicated prophylaxis is required; or

iv. Patient has had condomless anal intercourse with a person from a high HIV prevalence country or high-risk group whose HIV status is unknown

The Special Authority application form for PEP can be found **here**

PEP following occupational HIV exposure

Patients who have been exposed to HIV in an occupational setting, e.g. a needlestick injury in healthcare, can only be prescribed funded PEP by a named specialist, e.g. a sexual health or infectious diseases physician.[13] Patients should be urgently referred for an acute medical assessment. PEP recommendations following occupational exposure are included in Table 3. N.B. Any sexual activity is considered non-occupational exposure under the current guidelines. Primary care clinicians can prescribe PEP to sex workers following a potential HIV exposure.

Further information regarding evaluation and management of occupational HIV exposures is available in the NZSHS PrEP and PEP guidelines for Aotearoa New Zealand (2023), available from: **www.nzshs.org/guidelines/**

Who should receive PEP?

Patients who present following a potential HIV exposure should have their risk of HIV transmission assessed.[10] This can be calculated by multiplying the estimated risk of the specific exposure event (based on the mode of exposure) by the estimated risk of the source being HIV-positive (if their HIV status is not known), and offering PEP if this risk is > 0.001.[10] Tables containing these risk estimates can be found **here (Tables 9.1 and 9.2 in the NZSHS guideline)**.

In general, risk can be based on the type of sexual exposure and whether the HIV status is known. Advice on situations requiring PEP is available in Table 3, however, multiple patient factors can influence the risk of HIV transmission. Clinical evaluation should include a history of the recent exposure as well as information about the source person, if available.

Following this evaluation, PEP should be prescribed if it is clearly indicated. If the decision to prescribe PEP is uncertain, or the mode of exposure is not covered in Table 3, discussion with an infectious diseases or sexual health physician is recommended.

Clinical evaluation of a patient presenting for PEP should include:[10]

The exposure

- ☐ When the exposure occurred (date and time)
- ☐ Mode of exposure, including any factors that may influence or contribute to risk of transmission, e.g. involvement of blood or body fluids, trauma, any first aid that was carried out

The risk of transmission may also be influenced by other factors including:

- The viral load of the HIV-positive source; risk increases with increasing plasma viral load
- Presence of concurrent STIs
- Any breaches in genital or anal mucosal integrity, e.g. cuts or tears
- If ejaculation occurred during receptive intercourse
- Whether the HIV-negative person is circumcised; the odds of HIV infection via insertive anal intercourse are reduced by 23% in MSM who have undergone circumcision[19]
- Location of injury and type of needle involved (if needlestick injury)

The patient potentially exposed to HIV

- ☐ Date and result of last HIV test
- ☐ Any other potential HIV exposures since the patient's last HIV test
- ☐ Alcohol and drug use (current and previous)
- ☐ History of PrEP or PEP use
- ☐ Current STI status
- ☐ Pregnancy risk, contraception and lactation, if applicable (emergency contraception should be offered depending on circumstances)
- ☐ Medical history, specifically hepatitis B and C, renal function and psychiatric history
- ☐ Current medicines

Patients who are identified as having hepatitis B or C should be discussed with a sexual health or infectious diseases physician, or hepatologist before PEP is prescribed.

The source

- ☐ HIV status, if known
- ☐ General information, e.g. gender, country of origin

Contacting the source is not always possible or practical

PEP is more effective the sooner it is initiated following HIV exposure.[10] Contacting the source may aid in establishing the risk of transmission, however, this is not always possible in a timely manner and **PEP should be prescribed without delay**.[10]

Table 3. PEP recommendations based on mode of exposure. *Adapted from NZSHS PrEP and PEP guidelines (2023).*[10]

	Source known HIV-positive		Source of unknown HIV status	
	Detectable or unknown viral load	**Undetectable viral load**	**Source is MSM or from high-prevalence country**	**Source from a low prevalence population**
Sexual exposure				
Receptive anal sex	Three medicines	Not recommended	Two medicines	Not recommended
Insertive anal sex (circumcised and uncircumcised)	Three medicines	Not recommended	Consider two medicines	Not recommended
Receptive vaginal sex	Three medicines	Not recommended	Consider two medicines[a]	Not recommended
Insertive vaginal sex	Three medicines	Not recommended	Not recommended	Not recommended
Oral sex	Not recommended[b]	Not recommended	Not recommended	Not recommended
Occupational and other exposures PEP for an occupational exposure must be prescribed by a named HIV prescriber. Patients who present in primary care requiring PEP following an occupational HIV exposure should be urgently referred for an acute medical assessment.				
Shared injecting equipment	Three medicines	Three medicines[c]	Consider three medicines	Not recommended
Occupational needlestick injury	Three medicines	Three medicines[c]	Generally not recommended[d]	Not recommended
Mucosal exposure/ splash injury to infectious fluids	Three medicines	Generally not recommended[e]	Generally not recommended	Not recommended
Human bite	Not recommended[f]	Not recommended	Not recommended	Not recommended
Needlestick injury from a discarded needle in the community	Not applicable	Not applicable	Not recommended	Not recommended

a. There should be a lower threshold for PEP if HIV source is from a high-risk group or normally resides in a country with a high HIV prevalence, there is damage to mucosa, there were multiple exposures within the 72-hour window or the presence of STIs

b. PEP should be considered following receptive oral sex if there is damage to their oral mucosa and ejaculation occurred

c. PEP is recommended in this situation, however, the risk of transmission is expected to be low

d. PEP should not be withheld while awaiting results of HIV testing if the source is from a group that has a high prevalence of HIV infection. If the source cannot be tested or identified, PEP should be considered on a case-by-case basis, following discussion with an infectious diseases physician.

e. PEP may be offered in an occupational exposure depending on individual patient circumstances

f. PEP may be appropriate for the victim in situations where the perpetrator is known to be HIV-positive with a viral load > 1,000 copies/mL, blood was visible in the perpetrator's saliva and the bite has resulted in a severe or deep tissue injuries

If the source is contactable, ask for consent to contact their general practitioner (or other relevant health professional) about their HIV status, current viral load, treatment and medical history, e.g. hepatitis B and C status.[10] If the source is prescribed PrEP, ask about adherence; poor or inconsistent adherence may increase the risk of transmission, and therefore the need for PEP.[10]

Best practice tip: PEP may also be appropriate for patients who are currently prescribed PrEP but report poor adherence, if they present within 72 hours of a potential HIV exposure.[10]

Relevant investigations should not delay provision of PEP

Patients who present following a potential HIV exposure should undergo a baseline and follow-up HIV test (Table 4). Other investigations are determined by mode of exposure, e.g. STI testing for sexual contact.

Initiate PEP as soon as possible; do not delay treatment while contacting the potential HIV source or awaiting results of baseline investigations.[10]

Two or three medicine PEP regimens are available

Patients who require PEP should be prescribed a 28-day course of either a two medicine or three medicine regimen, depending on the mode of exposure (Table 3).

Two-medicine regimen:

Tenofovir disoproxil 245 mg with emtricitabine 200 mg (one tablet) once daily, for 28 days (unapproved indication)

Three-medicine regimen:

Tenofovir disoproxil 245 mg with emtricitabine 200 mg (one tablet) once daily **plus** dolutegravir 50 mg once daily, for 28 days (unapproved indication)

There is no clear evidence that one regimen is more beneficial than the other, however, the earlier either regimen is initiated the more effective it is likely to be.[10] A follow-up appointment should be arranged for after completion of the course (four weeks).[10]

Dolutegravir is the third PEP medicine, if required

Dolutegravir is recommended as part of the three-medicine PEP regimen for exposures with a known HIV-positive source (unapproved indication).[10] It is a HIV integrase strand transfer inhibitor and is generally well tolerated with once daily dosing, however, twice daily dosing may be required in patients taking medicines that induce CYP3A4 enzymes, e.g. carbamazepine, phenytoin, phenobarbital, rifampicin.[10, 20] Dolutegravir has also been shown to increase metformin plasma levels when taken concurrently; dose adjustment or more frequent monitoring of glycaemic control may be required.[10, 20] Patients who are prescribed dolutegravir should be advised to take it at least two hours before or six hours after antacids, and calcium or iron supplements.[10, 20]

Information about potential interactions between PEP and other medicines is available on the New Zealand Formulary interactions checker: **www.nzf.org.nz/nzf_1**. An interactions checker specific to HIV medicines is also available from the University of Liverpool: **www.hiv-druginteractions.org/checker**.

Table 4. Laboratory testing recommendations for initiation and follow-up of patients taking PEP. *Adapted from NZSHS PrEP and PEP guidelines (2023).*[10]

Investigation	Baseline	4 – 6 weeks	12 weeks
HIV serology	✓	✓	✓
Full STI screen	✓	✓	✓
Serum creatinine (for eGFR)	✓		✓
Hepatitis B and C	✓		✓
Full blood count	✓		
Liver function tests	✓		
Pregnancy test for people of child-bearing potential	✓	✓	

PEP in patients with impaired renal function

While the risk of decreased renal function is low with a 28-day course, avoid tenofovir disoproxil in patients with a creatinine clearance < 50 mL/min*.[10] Patients who cannot take tenofovir disoproxil due to reduced renal function may be prescribed a PEP regimen containing zidovudine and lamivudine (neither medicine is approved for this indication) following discussion with a sexual health or infectious diseases physician; dose adjustments may be required.[10] A third antiretroviral can be added to this regimen if indicated.[10]

* Tenofovir disoproxil should be avoided in patients with a creatinine clearance < 60 mL/min when used as part of PrEP.[9] Guidelines recommend using creatinine clearance to assess renal function, however, using laboratory reported eGFR may be more practical in primary care.[10]

A creatinine clearance calculator is available from: **nzf.org.nz/nzf/resource/Creatinine%20Clearance%20Calculator.htm**

Patient information when prescribing PEP

Before PEP is prescribed, patient discussions should include:

PEP is not 100% effective. Patients should be informed that while PEP lowers the risk of HIV infection, it is not 100% effective and needs to be taken as recommended to have the best chance of success, e.g. taken within 72 hours of exposure (but ideally 24 hours) and taken every day at the same time.[10] Advise the patient that a follow-up HIV test and in-person assessment is required after completion of PEP to confirm their seronegative status and again, three months after exposure.[10]

Symptoms and signs of HIV infection. Patients should seek medical attention on the rare chance they develop any symptoms or signs of acute HIV infection which include fever, sore throat, fatigue, headache, rash, myalgia and lymphadenopathy; these can occur any time up to six weeks after exposure.[5, 10] Some patients with acute HIV infection may be asymptomatic.[10]

Risk reduction. It is safest to implement strategies that minimise the potential risk of HIV transmission between the patient and others until they receive a negative test result, e.g. wearing condoms or abstaining from sexual activity, not sharing injecting equipment, not donating blood.[10]

PrEP may be appropriate. Patients who are likely to be at risk of ongoing HIV exposure may benefit from PrEP.[10] If required, this can be initiated at the completion of the 28-day PEP course.[10]

Additional resources

- The New Zealand Sexual Health Society (NZSHS) PrEP and PEP guidelines for Aotearoa New Zealand (2023) are available from: **www.nzshs.org/guidelines/**
  - Summary flow charts with key information for prescribing PrEP and PEP are available from: **www.nzshs.org/guidelines/**
- A list of pharmacies that may stock PrEP and PEP is available from: **www.healthpoint.co.nz/pharmacy/?serviceArea=im%3A1550889** (contact the pharmacy first to confirm stock availability)
- Burnett Foundation Aotearoa has produced online learning modules to aid primary care clinicians when engaging with MSM patients, prescribing PrEP and managing STIs. The modules are free (you must set up an account first) and available from: **www.burnettfoundation.org.nz/workforce-development/#More**
  - Patient-focused resources are also available from Burnett Foundation Aotearoa website

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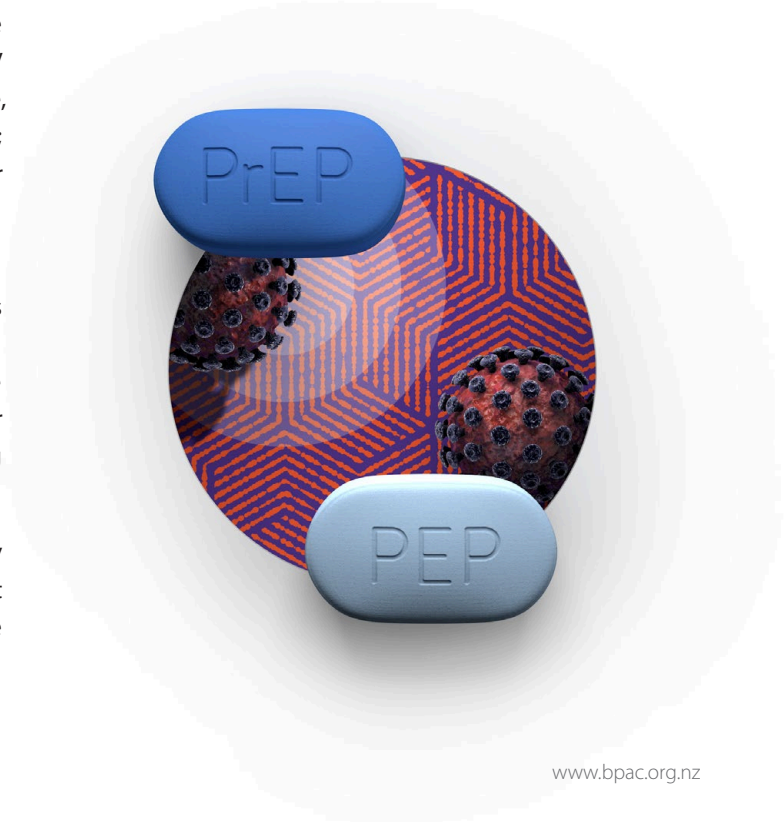

Non-judgemental communication is critical

In the 2020 Burnett Foundation Aotearoa Big Gay Sex Survey, 41% of people not currently taking PrEP indicated that they felt uncomfortable discussing PrEP with a doctor or nurse.[21] Potential reasons for this include previous negative interactions with healthcare professionals, anticipated stigma or discrimination, concerns about confidentiality or an assumption that the person's sexual orientation or behaviour is not relevant to the health service they are requesting.[22] MSM who do not feel comfortable engaging with their primary care provider may miss out on sexual health care and be at higher risk of poor sexual health outcomes, e.g. males who do not disclose their sexual orientation to their healthcare provider are less likely to undergo regular HIV testing.[22]

An open, safe and non-judgemental primary care service is required to disclose, assess and manage MSM sexual health effectively. Steps that primary care providers can take to improve their communication with MSM as well as ensuring their patients feel safe and accepted at the medical clinic include:

- **Asking for consent** – the patient must agree to undergo a sexual health check
- **Normalise sexual health checks** – clinicians should reinforce that these assessments are a routine part of healthcare, e.g. "*We ask all our patients about their sexual health. Would you be okay with me asking you a few questions about…*"
- **Displaying/promoting services and resources relating to MSM health issues** – approximately half of the participants in the Big Gay Sex Survey who were not taking PrEP did not know where they could access it.[21] Practices that openly promote MSM health issues, e.g. posters or leaflets in the waiting room, or advertise MSM services on websites, e.g. PrEP/PEP, may be seen as safer and more accepting and increase a patient's comfort when disclosing information.
- **Initiate PrEP conversations** – if a relevant risk factor for HIV infection is identified during a general or sexual health check-up, consider initiating a discussion about PrEP – it is often easier, and sometimes less anxiety-inducing, for the patient if the clinician brings it up first, e.g. "*… you mentioned your condom use is not as consistent as you'd like when you have been drinking alcohol. Has anyone talked to you about PrEP?*"
- **Reminding the patient about doctor-patient confidentiality** – do not assume that MSM have revealed aspects of their lives to the people around them, e.g. family and friends. If the healthcare provider cares for multiple family members, patients may feel less anxious to reveal certain details of their lives if they are reminded that any information they discuss is confidential.
- **Sign-posting during discussions** – patients may be more inclined to answer questions regarding their sexual health or HIV risk if they understand why the questions are being asked, e.g. "*… certain types of sexual contact are higher risk for HIV transmission than others, and to accurately assess your risk, it would be helpful to know…*"
- **Using inclusive language** – not everyone who is MSM identifies as gay, bisexual or he/him; avoid using labels and assumed pronouns when conducting a sexual health assessment until asking what the patient prefers, e.g. when enquiring about a recent sexual encounter, refer to the partner as "*they*" until you have asked "*What gender was/is that person?*"
- **Asking about sexual violence** – MSM may be at higher risk of sexual violence. Pooled data from the New Zealand Crime and Victims surveys between 2018 and 2022 found the likelihood of people who identified as gay, bisexual and lesbian experiencing sexual violence at some point in their lives (56%) was more than double that of the general population (24%).[23] Remain vigilant for **indicators of intimate partner violence** when conducting sexual health check-ups and ask the patient directly, if safe and appropriate to do so.

The language used by clinicians is known to influence a person's engagement in sexual health measures such as STI testing. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has published guidelines on preferred terminology, available from: **www.unaids.org/en/resources/documents/2015/2015_terminology_guidelines**

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