HIV Pre-Exposure Prophylaxis (PrEP): a how-to guide

Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) is a daily oral tablet that, when taken as prescribed, can greatly reduce new HIV infections as part of a combination prevention strategy. HIV PrEP (emtricitabine with tenofovir disoproxil) is fully subsidised with Special Authority approval for people at high risk of HIV infection.

KEY PRACTICE POINTS:

- If taken daily, HIV PrEP (oral emtricitabine with tenofovir disoproxil) reduces the risk of HIV infection by 99%
- Treatment is subsidised for HIV-negative male or transgender people who have sex with males and have multiple risk factors for HIV infection; OR, for HIV-negative people with partners who have a detectable HIV viral load
- Initial testing and monitoring recommendations for HIV PrEP treatment are substantial and include screening for sexually transmitted infections, testing for hepatitis, and monitoring renal and hepatic function
- Continuing to promote the consistent and correct use of condoms to prevent other STIs is an important aspect of treatment
- From 1 April, 2019, a new brand of emtricitabine with tenofovir disoproxil (Emtricitabine/Tenofovir Disoproxil, supplied by Teva) is available fully subsidised, and will be the sole subsidised brand from 1 September, 2019, replacing Truvada.

The goal to eradicate new HIV infections in New Zealand

The treatment of HIV infection has progressed enormously since the first cases of Acquired Immune Deficiency Syndrome (AIDS) were described in 1981.[1] Before the discovery of antiretroviral medicines, people with HIV would experience a progressive decline in T4 lymphocytes ("helper T cells").[1] These cells have the CD4 molecule on their surface which acts as the primary receptor for HIV infection.[1] Without treatment, the patient's CD4+ T cell count would decline over approximately five to ten years to the point where they developed AIDS and became highly vulnerable to life-threatening infections.[1] Following the advent of antiretroviral medicines the prognosis of people infected with HIV improved substantially. Diagnoses of AIDS have dropped dramatically in countries with subsidised access to antiretrovirals and the life expectancy of a 20-year old infected with HIV today is approximately 70 years.[1] Another advantage of antiretrovirals is that they can reduce the patient's HIV load to a level where they can no longer transmit the infection to other people.

The strategies to prevent new HIV infections

The goal in New Zealand is to eradicate new HIV infections by 2025.[2] A combination prevention strategy is being implemented to achieve this:

1. Consistent and correct use of condoms; the use of condoms decreases the risk of acquiring HIV infection by approximately 90%[3]
2. Regular testing, particularly focused on those at increased risk of HIV and STIs, e.g. men who have sex with men (MSM)
3. Early diagnosis and prompt treatment of people living with HIV to reduce their viral load and therefore avoid transmitting the infection to others
4. Targeted use of HIV Pre-Exposure Prophylaxis (PrEP) for groups at high-risk of HIV infection, i.e. MSM who do not regularly use condoms or people with a partner who has a detectable HIV viral load

The combined approach of condoms, regular testing, early treatment and HIV PrEP has been effective for groups of people with ready access to healthcare. For example, the New South Wales HIV Strategy in Australia has reported a 49% decrease in the number of Australian-born MSM diagnosed with early-stage HIV infections in the first half of 2018.[4] However, the lack of a similar outcome for other groups, e.g. Aboriginal Australians or recent immigrants, highlights the importance of equitable access to healthcare for the success of this approach.

HIV PrEP is fully subsidised for high-risk populations

New Zealand became one of the first countries in the world to fully subsidise oral emtricitabine with tenofovir disoproxil for HIV infection prophylaxis under Special Authority approval in March, 2018.[5] HIV PrEP is a daily oral tablet containing 200 mg emtricitabine and 245 mg tenofovir disoproxil. It greatly reduces the risk of HIV infection when taken as prescribed.[6]

Emtricitabine and tenofovir disoproxil are reverse transcriptase inhibitors that prevent a key step in the HIV replication cycle.[7] These medicines cannot eliminate HIV from individuals with an established infection.

Emtricitabine with tenofovir disoproxil can be co-prescribed in combination with other antiretrovirals for the treatment of HIV. It can also be used for Post-Exposure Prophylaxis (PEP) within 72 hours of a potential exposure to HIV (see: "HIV Post-Exposure Prophylaxis [PEP]").

PrEP is highly effective when taken exactly as prescribed

Seven days after beginning daily treatment with PrEP a person's risk of infection via rectal exposure to HIV is almost entirely eliminated;[8] a few extra days of PrEP may be required for vaginal and cervical tissues to be maximally protected from vaginal HIV exposure. PrEP is continued for as long as the patient remains at risk (see: "Monitoring treatment and maintaining adherence"). Condoms are strongly recommended for at least the first seven days of treatment.

The risk of HIV infection is reduced by 99% with perfect adherence to PrEP, i.e. if the medicine is taken at the same time of day, every day.[6] The level of protection from rectal HIV infection provided by PrEP falls to 96% in people taking four doses per week and 76% in those taking two doses per week.[6] Strict adherence to daily PrEP dosing is required to provide protection from vaginal HIV infection.[8] If a patient who has been adherent to daily PrEP withdraws from treatment or forgets to take their medicine, the protection provided by PrEP persists for approximately seven days following the last dose.[8]

Continue to encourage the consistent use of condoms

It is important that patients who are prescribed PrEP understand that they will only be protected against infection with HIV. Encouraging adherence to HIV PrEP and continuing to promote the consistent and correct use of condoms to prevent other STIs is essential.

A new brand of HIV PrEP, subsidised from 1 April, 2019

From 1 April, a new brand of PrEP is available fully subsidised, and will have sole supply in New Zealand from 1 September, 2019. Emtricitabine/Tenofovir Disoproxil (supplied by Teva) contains the same medicine combination and dose as the other subsidised brand of PrEP, Truvada. There is a difference in the tenofovir disoproxil salt between the brands; the Teva formulation contains tenofovir disoproxil succinate, and Truvada contains tenofovir disoproxil fumarate. However, both formulations are equivalent to 245 mg tenofovir disoproxil.

It is recommended that PrEP is prescribed using the generic medicine name; emtricitabine + tenofovir disoproxil. From 1 June, 2019, the subsidy of Truvada will be reduced and the brand will be delisted from 1 September, 2019. The brand change should be discussed with patients who are currently using Truvada.

N.B. Teva is not the brand name of this medicine, it is the supplier (sponsor). Care must be taken not to inadvertently prescribe Tenofovir Disoproxil alone, also supplied by Teva.

HIV in New Zealand: where are we at?

New HIV infections in New Zealand dropped in 2017, for the first time in six years.[9] However, it is too early to tell if this is the beginning of a downward trend. In 2017, there were 197 people with new HIV infections recorded in New Zealand, 38 of whom had been previously diagnosed overseas.[9] There are approximately 3,500 people infected with HIV living in New Zealand.[10]

Most new HIV infections occur in men who have sex with men

HIV infections predominantly occur in MSM,[8] who accounted for the majority of those diagnosed with locally acquired infections in 2017 (Table 1).[9] There are multiple reasons why MSM are at increased risk of HIV infection compared with heterosexual people:[1, 11]

- Receptive anal intercourse has a higher risk of HIV infection than vaginal intercourse because the rectal mucous membrane separating deposited semen from cells susceptible to infection is thinner and the surface area of mucosa exposed to the virus is much larger
- The ratio of MSM in New Zealand who are infected with HIV is higher than the general population; 37 times higher compared to heterosexual males
- 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

It appears that HIV infection is being diagnosed earlier in New Zealand MSM, allowing for prompt treatment, potentially limiting the spread of the disease and preventing progression to AIDS. This conclusion is supported by the average CD4+ count at diagnosis increasing since 2006, suggesting a less depleted immune system in those diagnosed.[9] Injectable drug use is now a rare cause of HIV infection, with only one recorded case in 2017, due to the early and successful implementation of needle-exchange programmes in New Zealand.[9]

Heterosexual females are at higher risk than heterosexual males

Among heterosexuals, females have twice the risk of males of being infected by a partner with HIV because the virus is concentrated in seminal fluid.[1, 3] However, the number of cases of HIV infection recorded in heterosexual males* and females was the same (12) in New Zealand in 2017 (Table 1).[9]

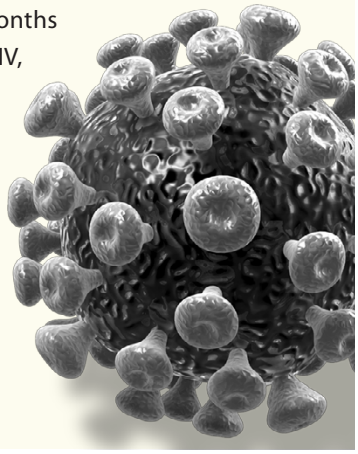
* It is possible that some cases of HIV infection reported in heterosexual males were actually in MSM who did not disclose their same-sex contact

Table 1: Patient characteristics for new HIV cases in New Zealand in 2017[9]

MSM cases (n=128)	**Heterosexual cases** (n=24)
Ethnicity ■ European – 54% ■ Asian – 22% ■ Māori – 6% ■ Pacific peoples – 6% ■ Other/unknown – 12% Location ■ Auckland – 43% ■ Wellington – 22% ■ North Island other regions – 12% ■ South Island – 9% ■ Overseas – 7% ■ Unknown – 7%	Gender ■ 12 males, 12 females Ethnicity ■ Asian – 42% ■ European – 25% ■ Māori – 8% ■ African – 8% ■ Other – 17%

AIDS is decreasing in New Zealand

HIV disease is a spectrum that begins with acute infection, that if left untreated, progresses to AIDS, which is invariably lethal due to opportunistic infections and cancers.[1] In New Zealand, deaths due to AIDS peaked at approximately 70 per year in the late 80s and early 90s, and although there have been fluctuations in the rate there has been a consistent downward trend ever since. Latest figures from 2017 show 12 people were notified with AIDS (11 males, 1 female).[9] Five of those were diagnosed with AIDS within three months of being diagnosed with HIV, suggesting that they had been infected with HIV for a substantial period of time.[9] Increasing the uptake of regular HIV testing is crucial to avoid diagnosis at the stage of AIDS.



How to prescribe PrEP

The Special Authority criteria for HIV PrEP are derived from the Australian Health In Men (HIM) study, that identified the key factors associated with an increased risk of infection with HIV in MSM.[12] Testing is required, both prior to and following initiation of PrEP to receive subsidised treatment. It is estimated that 5,800 people in New Zealand will be eligible for PrEP, including 18% of all sexually active MSM.[13]

Special Authority approvals need to be renewed every three months

Special Authority approvals for HIV PrEP are valid for three months and must be renewed every three months thereafter.

Special Authority initial applications and renewals for subsidised PrEP can be submitted by any relevant practitioner who is confident in their knowledge of PrEP and ability to safely manage the patient's treatment.

The Special Authority application form for HIV PrEP can be found here: **www.pharmac.govt.nz/latest/SA1842.pdf**

Further information on prescribing HIV PrEP is available from: **www.pharmac.govt.nz/medicines/my-medicine-has-changed/prep-for-hiv/**

Initiating subsidised PrEP

To initiate subsidised PrEP patients must have first tested negative for HIV and:

Meet ***EACH*** of the following characteristics:

- Male or transgender
- Has sex with males
- Likely to have multiple episodes of anal intercourse without condoms in the next three months

AND have at least one of the following:

- At least one episode of receptive anal intercourse with a male partner without condoms in the last three months; or
- A diagnosis of rectal chlamydia, rectal gonorrhoea or infectious syphilis in the last three months; or
- Use of methamphetamine* in the last three months

OR meet ***EACH*** of the following characteristics:

- Has a regular partner who has an HIV infection
- The partner has a detectable viral load or is untreated for HIV
- Condoms are not consistently used

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

Testing before initiating PrEP

Before applying for Special Authority approval the patient must have tested negative for HIV (see: "HIV Post-Exposure Prophylaxis [PEP]" for information on managing patients at high risk of HIV infection due to recent exposure).

Guidelines and sexual health specialists also recommend additional testing, including (Table 2):

- 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 (urine, rectal, vulvovaginal and throat swabs as appropriate)
- Estimated glomerular filtration rate (eGFR), serum phosphate and creatinine, urine dipstick (to detect protein), albumin:creatinine ratio
- Full blood count
- Liver function tests
- Pregnancy testing in people with childbearing potential

People with chronic hepatitis, can take PrEP, however, testing prior to initiating treatment is recommended as there may be an increased risk of hepatic adverse effects.[8] Consultation with a hepatologist or infectious diseases physician experienced in treating chronic hepatitis is recommended before starting HIV PrEP in patients with hepatitis B or C.[8] Testing for hepatitis B virus (HBV) is particularly important because emtricitabine and tenofovir disoproxil are both active against HBV and withdrawal of PrEP can lead to reactivation of HBV and hepatic injury.[8] Immunisation against HBV, and demonstration of immunity, is recommended for all MSM who test negative for HBV prior to initiating PrEP.[8] Ongoing testing for HBV is not necessary in immune patients unless there is an unexplained elevation in alanine aminotransferase. Immunisation against hepatitis A virus is recommended for those who are not immune as it can be easily sexually transmitted among MSM and transgender people who have sex with males, however, vaccination is not subsidised in New Zealand.

People with a bacterial STI, e.g. chlamydia, gonorrhoea and syphilis, can take PrEP and this should not be a reason to delay initiation.[8] People taking PrEP are at high risk of STIs other than HIV. Therefore, advice about use of condoms and initial and ongoing testing is required to detect any STIs, which should be treated promptly; PrEP should be continued while the patient is being treated.

PrEP is contraindicated in people with an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73m^2, as treatment with tenofovir has occasionally been associated with

Table 2: Laboratory testing recommendations for initiation and follow-up of patients taking HIV PrEP[8]

Investigation	Baseline	One month after initiation	Every three months	Additional frequency
HIV and full STI screen*	✓	✓	✓	–
eGFR, phosphate, urine dipstick and albumin:creatinine ratio†	✓	–	–	At first follow-up and every six months thereafter‡
Hepatitis A and B**	✓	–	–	–
Hepatitis C	✓	–	–	At least every 12 months
Full blood count	✓	–	–	–
Liver function tests	✓	–	–	Every 12 months
Pregnancy test for people of child-bearing potential	✓	✓	✓	–

Required for Special Authority subsidy Recommended

* Blood tests for HIV and syphilis and NAAT for chlamydia and gonorrhoea (urine, rectal swab, vulvovaginal swab, throat swab)

† More frequent monitoring may be appropriate for patients who are aged over 40 years or who have an eGFR < 90 mL/min/1.73m^2, or those with hypertension or diabetes or who are taking non-steroidal anti-inflammatory drugs (NSAIDs) long-term

‡ Testing every 12 months is required for Special Authority renewal

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

nephrotoxicity.[8] Following initiation of PrEP, it is recommended that the patient's serum creatinine, eGFR, serum phosphate, urine dipstick (to detect protein) and albumin:creatinine ratio* be assessed at three months and at six-monthly intervals thereafter.[8] More frequent monitoring may be appropriate for patients who are more susceptible to clinically significant reductions in eGFR or who are at risk of renal disease, including those who:[8]

- Are aged over 40 years; studies have shown that the use of PrEP in this age group is associated with a faster decline in renal function[14, 15]
- Have an eGFR < 90 mL/min/1.73m^2
- Are taking another nephrotoxic medicine long-term, e.g. non-steroidal anti-inflammatory drugs (NSAIDs)
- Have co-morbidities such as hypertension, diabetes or hepatitis C infection
- Have a low bodyweight

* HIV PrEP guidelines recommend investigating urine protein:creatinine ratio, but nephrology expert opinion is that this test may miss early changes and albumin:creatinine ratio would be a more sensitive measure. A pragmatic approach is to start with a urine dipstick and if protein is detected, request a urine protein:creatinine ratio, otherwise request an albumin:creatinine ratio.

Effective contraception should be provided to all people of child-bearing potential who are taking PrEP and do not wish to become pregnant, including transgender males with female reproductive organs, if they have sex with males.[8] PrEP can be taken during pregnancy after balancing the risks and benefits of treatment; there is an increased risk of HIV infection during pregnancy, but lower neonate bone mass density is a potential adverse effect.[8]

Renewing subsidised PrEP

To renew subsidised PrEP (required every three months) *ALL* of the following must apply:

- Applicant must have a current knowledge of safety issues and be competent to prescribe PrEP
- Patient must be confirmed HIV negative in the past two weeks and have had a full STI screen, including syphilis testing
- Renal testing (creatinine, phosphate, urine dipstick and albumin:creatinine ratio) in the past 12 months
- Patient must be advised on the risk of infection with STIs and how to reduce these risks, e.g. the correct and consistent use of condoms

AND the patient continues to meet ***ALL*** criteria of the initial Special Authority application.

Testing before renewing PrEP

Follow-up consultations are necessary before renewing subsidised PrEP treatment. This needs to be carefully scheduled as the patient must have a full STI screen, including HIV, syphilis, chlamydia and gonorrhoea in the two weeks prior to applying for renewal of Special Authority approval (Table 2). The recommended testing regimen for renewal of PrEP is:

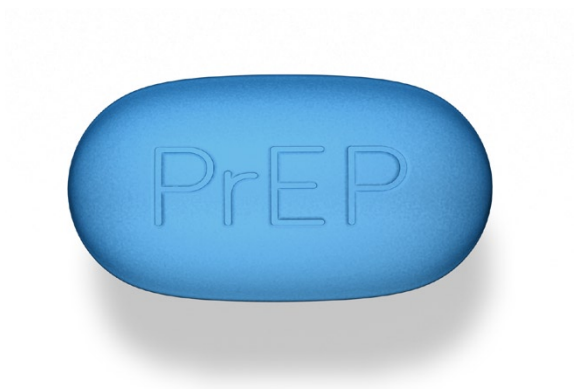
- Blood tests for HIV and syphilis no more than two weeks before renewing the Special Authority
- Multi-site NAAT for chlamydia and gonorrhoea (urine, rectal, vulvovaginal and throat swabs as appropriate) within two weeks of each renewal
- Serum creatinine, eGFR, serum phosphate, urine dipstick and albumin:creatinine ratio tests at first follow-up and every six months thereafter; patients may require ongoing three-monthly testing
- Liver function test every 12 months, or more frequently if indicated‡
- Hepatitis C test every 12 months‡
- Pregnancy test in people of childbearing potential one month after initiation and every three months thereafter‡

‡ Not required for Special Authority approval

Monitoring treatment and maintaining adherence

The adverse effects associated with PrEP are generally mild and transient. Gastrointestinal symptoms, e.g. nausea, vomiting, abdominal pain, flatulence, diarrhoea, and headache are most frequently experienced.[8] These are most likely to be reported in the first month of treatment.[8]

There is an increased risk of hepatic adverse effects in patients with chronic hepatitis. The bone density of patients taking PrEP may be reduced slightly and older patients with multiple risk factors for fractures, e.g. high alcohol consumption, smoking, low body mass index (BMI), should be advised to reduce their alcohol intake, stop smoking, consume sufficient calcium, ensure adequate exposure to sunlight to maintain vitamin D levels and perform weight-bearing exercises.[8]



Managing declining renal function

Initiation of PrEP is contraindicated in patients with an eGFR < 60 mL/min/1.73m^2.[8] However, continued treatment may be possible if kidney function drops below this point, but only following discussion with a sexual health or infectious diseases physician with expertise in PrEP or a nephrologist. Potential options include:[8]

- Permanently withdrawing treatment
- Pausing treatment for a brief period, e.g. one month, to allow renal function to recover (during which time they will not be protected from HIV infection)
- Taking PrEP every second day (which might be less effective)

N.B. eGFR can be variable, e.g. due to the level of hydration, therefore, if testing indicates eGFR is < 60 mL/min/1.73m^2 consider repeating the test to confirm the result before withdrawing PrEP.

Interactions with other medicines and late-onset nephrotoxicity

Emtricitabine and tenofovir disoproxil predominately undergo renal excretion, therefore 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 (including those purchased over-the-counter).[8] Nephrotoxicity is rare in patients taking PrEP, although proximal tubular dysfunction can occur, therefore monitoring of renal function every six months is recommended.[8]

Information about potential interactions between PrEP and other medicines is available on the New Zealand Formulary interaction checker: **www.nzf.org.nz/nzf_10222**. An interactions checker specific to HIV medicines is also available from the University of Liverpool: **www.hiv-druginteractions.org/checker**

Encourage adherence to ensure ongoing protection

Patients should be educated about how PrEP works and understand that they will not be protected if they stop taking it. Discuss the potential adverse effects, e.g. gastrointestinal disturbances, and provide reassurance that these usually resolve within three months of initiating treatment. Recommend a routine for dosing, e.g. in the morning with toothbrushing, and identify and address any barriers to adherence, e.g. substance abuse or mental illness. Adherence should be assessed and encouraged at every consultation. If a dose is missed, advise the patient that they should take a tablet as soon as they remember, unless there are fewer than 12 hours until the next dose, in which case the missed dose can be skipped.[8]

Patients taking fewer than four doses per week are unlikely to be protected against HIV infection and withdrawal

of treatment is recommended if a patient consistently reports taking less than this (see below).[8]

Patient information on HIV PrEP is available from: **www.nzaf.org.nz/assets/ee-uploads/files/Ending_HIV_PrEP_Booklet_WEB.pdf** and **https://endinghiv.org.nz/stay-safe/prep**

Reducing the patient's risk of STIs

It is possible that some people may become complacent about STI prevention if they are taking PrEP. It is therefore important to reinforce that PrEP only protects against HIV and to discuss:[8]

- Any barriers to consistent condom use
- Reducing any substance misuse
- Identifying one or two steps that the patient can take to reduce their STI risk
- Acknowledging efforts by the patient to reduce their risk and to reinforce these successes

Patient information on HIV, including links to other support organisations and resources, is available from: **www.nzaf.org.nz/living-with-hiv/**

Withdrawing PrEP

Long-term treatment with PrEP may not be necessary for some patients, e.g. if they start consistently using condoms or they enter a mutually monogamous relationship with a partner who is HIV-negative. It is recommended that patients wishing to stop treatment continue taking PrEP for 28 days after their last potential exposure to HIV.[8] Subsidised PrEP can be reinitiated if the patient's risk of HIV infection increases in the future. Record the patient's HIV status, reasons for discontinuing treatment, adherence while being treated and risk-taking behaviour.[8] Any patient with chronic hepatitis B infection should be discussed with a hepatologist or infectious diseases physician with expertise in managing chronic HBV infection before withdrawing from PrEP, due to the risk of HBV reactivation.[8]

A webinar on HIV PrEP for primary care presented by Dr Vincent Cornelisse and Dr Massimo Giola is available from: **https://www.goodfellowunit.org/events/hiv-prep-update-primary-care**

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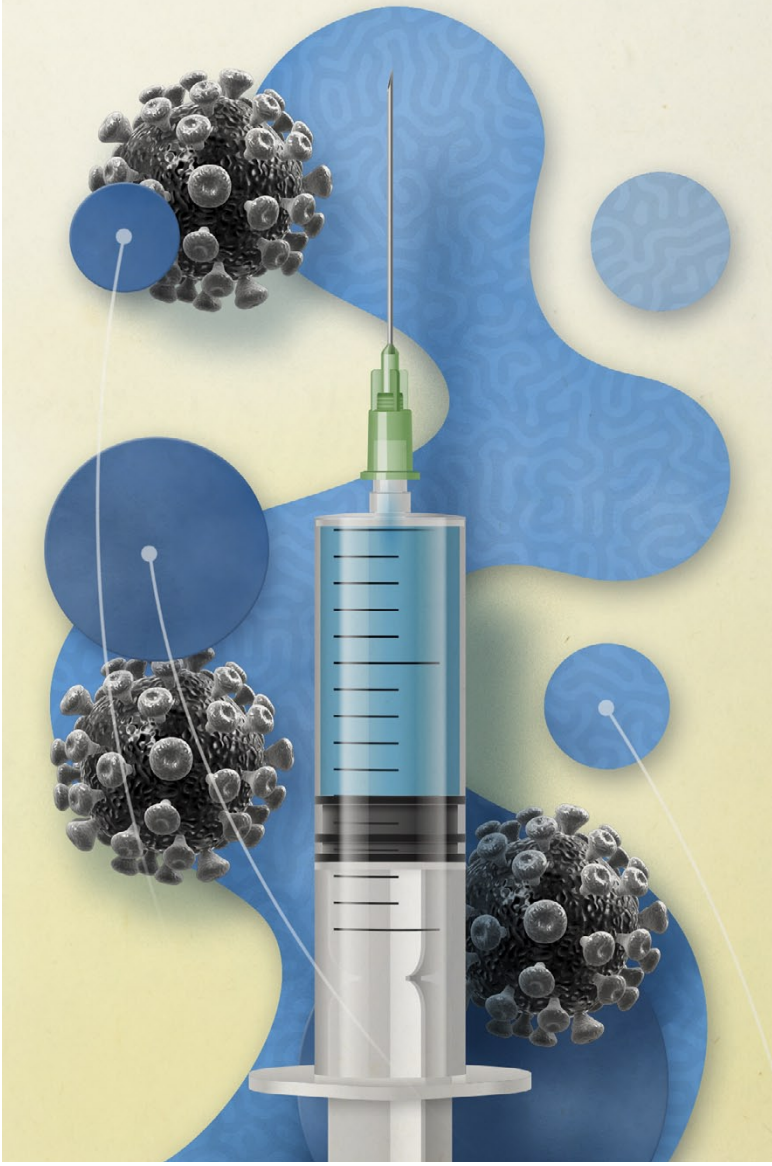
N.B. Expert reviewers do not write the articles and are not responsible for the final content.

HIV Post-Exposure Prophylaxis (PEP)

Emtricitabine with tenofovir disoproxil is also a first-line option* in the emergency treatment (within 72 hours) of a recent exposure to a potential source of HIV, including needle-stick injury, sexual assault or other high-risk sexual exposure.[16] A 28-day course of daily emtricitabine with tenofovir disoproxil, with or without an additional antiretroviral, may be prescribed fully subsidised with Special Authority approval.[16] Discussion with an infectious diseases physician or referral to the local emergency department is recommended.

N.B. The Special Authority application for PEP can only be made by a named HIV specialist and uses a different form than for PrEP.

* Not an approved indication for this medicine in New Zealand



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