Pharmaceutical Society of Australia

ashm
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine

Dispensing HIV pre-exposure prophylaxis (PrEP)

June 2018

Prescription presented for tenofovir disoproxil (TD)*/emtricitabine (FTC) for PrEP

Confirm PBS requirements

- Authority required (Streamlined) with maximum quantity of 30 units with 2 repeats (e.g. 90-day medication supply).
- Clinical criteria: The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australasian Society for HIV, Viral Hepatitis and Sexual health Medicine (ASHM) Guidelines.

AND

- Patient must have a negative HIV test result prior to treatment with PBS-subsidised therapy with this drug.
- Population criteria: Patient must be 18 years or older.
- Refer to www.pbs.gov.au for further information.[1]

Confirm HIV status

Confirm PrEP is being commenced within 7 days of the day the patient's HIV-negative test using a 4th-generation Ag/Ab test was performed.[2] This may be recorded on the prescription, the patient's My Health Record or verified through discussion with patient. This may mean that the clinician may permit the patient to start PrEP before the HIV result is known.

If the prescription is presented more than 7 days after the date of prescribing, consider the possibility of a recent high-risk exposure and refer the patient to the prescriber for further testing as appropriate.

Confirm hepatitis B and C status

Hepatitis B and C infection status should be documented by prescriber at baseline. Vaccination for hepatitis B is recommended for those not immune.[2] Patients can commence PrEP while the results of their baseline hepatitis B and C tests are pending.

*Tenofovir disoproxil includes tenofovir disoproxil fumarate, tenofovir disoproxil maleate and tenofovir disoproxil phosphate.

Review prescribed medicines

Pregnancy – PrEP may be used during pregnancy in women at substantial risk of HIV.[2] Key considerations include the following[2]:

- The risk of acquiring HIV is elevated during pregnancy in women at risk of acquiring HIV. If HIV is acquired during pregnancy, it can be transmitted to the fetus.
- Tenofovir disoproxil use for HIV treatment has not been associated with adverse pregnancy outcomes, although lower bone-mineral density in newborns has been reported in mothers who received antiretroviral therapy (especially regimens that include tenofovir disoproxil) whilst pregnant.
- One study has shown that women who became pregnant while using PrEP and who continued PrEP during pregnancy had no greater adverse pregnancy outcomes than women with no PrEP exposure. The infants of women who used PrEP throughout pregnancy had statistically significant smaller length (p=0.05) and head circumference (p=0.04) at one month compared to infants whose mothers had no exposure to PrEP during the pregnancy. However, at one year, there were no differences between these measures in the two infant groups.[3]

Breastfeeding – PrEP may be used during breastfeeding in women at substantial risk of HIV.[2] Key considerations include the following:

- The risk of HIV transmission to a breastfed infant is high during and soon after acute HIV infection (seroconversion) due to high viral load.[2]
- Experience with PrEP during breastfeeding is lacking, though tenofovir disoproxil/emtricitabine has been used by breastfeeding women being treated for HIV. There does not appear to be a safety-related reason for prohibiting PrEP during breastfeeding[2,4]
- Tenofovir disoproxil and emtricitabine are secreted in breast milk in minimal concentrations (0.3% and 2%, respectively, of the doses used for the treatment of HIV infection in infants).[2,5]

Patients with chronic active hepatitis B (HBV) infection:

- Tenofovir disoproxil and emtricitabine are active against both HIV and HBV infections.[2,6]
- There is a low risk of HBV flare-up upon PrEP discontinuation.[2,6] Adherence to daily PrEP is critical for preventing reactivation of HBV and reducing the risk of developing tenofovir-resistant HBV. Strict adherence to PrEP and ongoing monitoring of hepatitis B infection is required.
- Decision to cease PrEP in a patient with HBV should be overseen by the patient's treating clinician.

Patients with chronic renal failure – tenofovir disoproxil/emtricitabine should not be used for PrEP if estimated creatinine clearance is <60 mL/min.[7] Contact prescriber if creatinine clearance is <60 mL/min and consider referral to a clinician experienced with PrEP in patients with borderline renal function.

Potential drug interactions – tenofovir disoproxil and emtricitabine are primarily excreted by the kidney by a combination of glomerular filtration and active tubular secretion.[7] Consider interactions with medicines that affect renal function or compete for active tubular secretion.

Dose – tenofovir disoproxil/emtricitabine is approved by the Therapeutic Goods Administration (TGA) for PrEP as a single daily dose.[7] Other dosing schedules (e.g. on-demand) are not currently approved by the TGA. Encourage patients who may be experimenting with alternative dosing schedules to discuss their options with the prescriber.[2] Refer to ASHM PrEP Guidelines for further information.

Supply PrEP and provide counselling

Ensure patient privacy.[8]

Initiating PrEP:

Tenofovir disoproxil/emtricitabine must be taken for 7 consecutive days before high levels of protection against HIV are achieved, with consistent daily dosing thereafter.[2] Patients should not rely on PrEP for HIV prevention in the first 7 days of use.

Adverse effects:

- Headache, nausea and flatulence are common. These may decrease or disappear with continued use.[2,7] Non-prescription medicines can be used to relieve these effects if they are troublesome for the patient. Taking PrEP with a meal may also relieve these effects.
- Renal impairment—signs and symptoms include abnormal urinary output, anorexia, peripheral oedema. Requires urgent referral[2,9]
- Reduced bone density. Routine screening of bone density is not recommended, but people with risk factors for low bone density or a history of minimal trauma fractures should consider having a bone density scan.[2]

Refer if necessary
(with or without supply as appropriate)

Acute HIV infection signs and symptoms[11,13]:

- fever
- headache
- rash
- malaise
- tachycardia
- lymphadenopathy.

Not all people undergoing seroconversion/acute HIV infection will present with all or any of these signs or symptoms.

Adherence – critical to achieving maximum HIV prevention benefit of PrEP and reducing the risk of drug resistance in the event of HIV infection.[2] Counsel patients on how to take their medicines regularly and what to do if they miss a dose. Patients should take a single missed dose as soon as they remember it, unless it is almost time for the next dose. If it is <12 hours before the next dose is due, patient should skip the missed dose and continue with the regular dosing schedule.[2,7]

Sexually transmitted infections (STIs) – individuals at high risk of HIV infection are also at high risk of STIs. The presence of an STI (other than HIV) at baseline or during treatment should not delay the commencement and ongoing use of PrEP.[2]

Inform patients starting on PrEP about[2]:

- prevention of STI acquisition and transmission – (e.g. use of condoms)
- frequency of STI testing (every 3 months with prescriber)
- signs and symptoms of STIs and need for testing when signs or symptoms of STIs occur.

Monitoring – for ongoing PrEP use[2]:

- HIV testing using 4th-generation Ag/Ab test every 3 months.
- Renal function testing 3 months after commencement of PrEP and every 6 months thereafter.
- Hepatitis C testing at least every 12 months (or more frequently if necessary).
- Hepatitis B monitoring every 3–6 months for people living with chronic HBV infection.
- Pregnancy testing in women of child-bearing potential if pregnancy is suspected (e.g. missed period).

Discontinuing PrEP – daily PrEP should be continued for 28 days after the last high-risk sexual exposure.[2,10] Document the reason for PrEP discontinuation and any information provided about medication adherence.[2]

Restarting PrEP – consider referring patients who appear to have temporarily or permanently ceased PrEP (e.g. dispensing intervals >30 days) to the prescriber. All baseline evaluations should be repeated for any person restarting PrEP. Previous discontinuation of PrEP does not exclude the person from restarting PrEP (except if HIV seroconversion has occurred).[2]

Short-term use of PrEP – patients may take a course of PrEP for a discrete period of time (e.g. during travel to high-prevalence countries). Daily PrEP should be started 7 days before departure and continued for 28 days after the last high-risk HIV exposure.[2]

Non-adherence

A PrEP user who has not been adherent to PrEP and has had a recent high-risk exposure (within 72 hours) may require a course of post-exposure prophylaxis.[2] Refer to the prescriber immediately for assessment.

Sexually transmitted infections

Refer for screening (specifically gonorrhoea, chlamydia and infectious syphilis) and management according to the Australian STI Management Guidelines.[13]

Additional resources

Pharmaceutical Society of Australia. Dispensing practice guidelines. Canberra: PSA; 2017. At: www.psa.org.au/practice-support-and-tools/guidelines-and-tools

References

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