

# Pre-Exposure Prophylaxis for the Prevention of HIV Infection

## Background information

Emtricitabine / tenofovir disoproxil has now received European marketing approval for prevention of HIV in combination with other measures, because of a number of trials demonstrating considerable clinical effectiveness at preventing HIV infection. Pre-exposure prophylaxis (PrEP) may be taken as a daily dose or dosing around sexual activity (so called “event based” or “on-demand” dosing). Side effects such as headache, nausea / vomiting or diarrhoea may occur soon after commencing medication but will tend to subside within a few days. As a result, some people may opt to take medication continuously, although event based dosing (EBD) reduces the risk of renal toxicity that might arise from the drugs used for PrEP. Prior to commencing PrEP, people should have a baseline assessment of renal function with a creatinine clearance above 80ml/min. In individuals without risk factors for renal disease, it is recommended that renal function is monitored after 2 to 4 weeks of use, after 3 months of use and every 3 to 6 months thereafter. Hepatitis B status is also assessed (either evidence of vaccination or testing negative) and hepatitis B vaccination is advised where appropriate.

## CAA certificatory guidance

Applicants should be assessed as unfit for aeromedical certification / have their medical certificate suspended when starting PrEP.

Fitness can be reassessed 7 days after starting continuous PrEP or for EBD, with tenofovir and emtricitabine, after at least 2 doses taken at least a week apart with no evidence of disabling side-effects (fit 2 days after second dose if no side-effects and applicants should report any side-effects associated with future doses). Applicants should provide their aeromedical examiner (AME) with a copy of the baseline assessment results for renal function (for example, creatinine clearance).

Applicants should provide a copy to their AME of their monitoring results assessed 3 months after commencing PrEP.

Applicants should continue to undertake 3 to 6 monthly monitoring and inform their AME if there are any abnormalities associated with the monitoring tests (for example, renal function) and associated sexually transmitted infection (STI) follow-up.

It is recommended that people taking PrEP engage with Sexual Health Services to ensure HIV testing and testing for other STIs every 3 months.