

# Pre-Exposure Prophylaxis (PrEP) 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.

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 two to four weeks of use, after 3 months of use and every 3-6 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 should report any side-effects associated with future doses). Applicants should provide their AME with a copy of the baseline assessment results for renal function (e.g. 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 3-6 monthly monitoring and inform their AME if there are any abnormalities associated with the monitoring tests (e.g. renal function) and associated STI follow-up.

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