Checklist for Prescribers

Instructions: Complete checklist at each visit and file in individual's medical record.

Patient Initials: DOB: Gender: M ☐ F ☐ Age:

I have completed the following prior to prescribing Emtricitabine/Tenofovir disoproxil for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to startor is taking Emtricitabine/Tenofovir disoproxil for a PrEP indication:

Initial Evaluation

☐	Completed risk evaluation of uninfected individual
☐	Confirmed negative HIV-1 test immediately prior to initiating Emtricitabine/ Tenofovir disoproxil for a PrEP indication using a combined antigen/antibody test • If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status.
☐	Performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhoea
☐	If applicable, evaluated risk/benefit for women who may be pregnant or may want to become pregnant
☐	Performed HBV screening test
☐	Offered HBV vaccination as appropriate
☐	Prior to initiation confirmed estimated creatinine clearance (CrCl) **Uninfected adults** CrCl >80 mL/min. If CrCL<80 mL/min, use only if benefit outweighs risk. Not recommended if CrCl <60 mL/min. **Uninfected adolescents** Should not be used if CrCl <90 mL/min/1.73 m^2.
☐	Confirmed that the individual at risk is not taking other HIV-1 or HBV medications
☐	Confirmed that the individual at risk is not taking or has not recently taken a nephrotoxic medicinal product If concomitant use of Emtricitabine/Tenofovir disoproxil and nephrotoxic agentsis unavoidable, renal function should be monitored weekly.

Counselling

☐	Counselled that Emtricitabine/Tenofovir disoproxil for a PrEP indication should be used only as part of a comprehensive prevention strategy and educated on practicing safer sex consistently and using condoms correctly
☐	Counselled on the importance of adherence to daily dosing schedule
☐	Recommended to the individual to add a reminder to their mobile phone or any other device that can alert them when it is time to take Emtricitabine/Tenofovir disoproxil

☐	Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)
☐	Counselled on the importance of scheduled follow-up, including regular HIV-1 screening tests (e.g. at least every 3 months), while taking Emtricitabine/Tenofovir disoproxil for a PrEP indication to reconfirm HIV-1–negative status
☐	Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
☐	Discussed the importance of screening for sexually transmitted infections (STIs), such as syphilis and gonorrhoea, that can facilitate HIV-1 transmission
☐	Discussed known safety risks with use of Emtricitabine/Tenofovir disoproxil for a PrEP indication
☐	Provided patient materials to the individual at risk and reviewed this with them

Follow up

☐	Performed regular HIV-1 screening (e.g. at least every 3 months)
☐	Checked the individual's reported adherence (e.g. from the calendar on the Reminder Card)
☐	Reassessed the individual at each visit to ascertain whether they remain at high risk of HIV-1 infection. The risk of HIV-1 infection should be balanced against the potential for renal and bone effects with long-term use of Emtricitabine/Tenofovir disoproxil
☐	Discontinued Emtricitabine/Tenofovir disoproxil for PrEP if seroconversion has occurred
☐	Performed screening for STIs, such as syphilis and gonorrhoea
☐	Identified potential adverse reactions
☐	Performed renal monitoring as recommended In individuals without renal risk factors, renal function (creatinine clearance and serum phosphate) should be monitored after 2 to 4 weeks of use, after 3 months of use and every 3 to 6 months thereafter. In individuals at risk for renal impairment, more frequent monitoring of renal function is required. **Uninfected adults and adolescents** Please refer to Safety leaflet for prescribers, section "Emtricitabine/Tenofovir disoproxil related renal toxicity"
☐	Performed HBV screening test (if previously tested negative for HBV or had not received HBV vaccination)
☐	Recorded next follow-up appointment and HIV-1 screening test dates in the Reminder Card and provided this to the individual

Prescriber signature and name in print _____ **Date** _____

Local version 1.0

NCA approval date 22-Dec-2021

VIATRIS