CHECKLIST FOR PRESCRIBERS

Initiation of emtricitabine/tenofovir disoproxil for Pre-Exposure Prophylaxis (PrEP)

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

☐ 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 start or is taking emtricitabine/ tenofovir disopoxil for a PrEP indication.

Lab Tests/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)
CrCL >80mL/min. If CrCL <80mL/min, use only if benefit outweighs risk. Not recommended if CrCL <60mL/min.

☐ 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 agents is 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 practising safer sex consistently and using condoms correctly.

☐ Counselled on the importance of adherence to the 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 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.

☐ Reviewed the document 'Important Information About emtricitabine/ tenofovir disoproxil to Reduce the Risk of Getting Human Immunodeficiency Virus (HIV) Infection' with the individual.

☐ Provided patient material 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).

☐ 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 of renal impairment, more frequent monitoring of renal impairment is required.

☐ 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

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- *all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason*
- *all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼*

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website.