

## 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 disoproxil 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**

- Counselling 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.
- Counselling 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).
- Counselling 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](mailto: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.*

