✔ CHECKLIST FOR PRESCRIBERS

Initiation and follow up of emtricitabine/tenofovir disoproxil fumarate for Pre-exposure Prophylaxis (PrEP)

Instructions:

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

I have completed the following prior to prescribing emtricitabine/tenofovir disoproxil fumarate for a Pre-exposure Prophylaxis (PrEP) indication for the individual who is about to start or is taking emtricitabine/tenofovir disoproxil fumarate for a PrEP indication:

Initial Evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate 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 <u>adolescents</u>

  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 fumarate and nephrotoxic agents is unavoidable, renal function should be monitored weekly.

Counselling

- ☐ Counselled that emtricitabine/tenofovir disoproxil fumarate 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 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 fumarate
- ☐ 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 fumarate for a PrEP indication to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing emtricitabine/tenofovir disoproxil fumarate 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 fumarate for a PrEP indication
- ☐ 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)
- ☐ 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 fumarate
- ☐ Discontinued emtricitabine/tenofovir disoproxil fumarate 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 <u>and adolescents</u>

  Please refer to Safety leaflet for prescribers, section emtricitabine/tenofovir disoproxil fumarate 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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.yellowcard.mhra.gov.uk
Tel: +44 (0) 800 731 6789

Any suspected adverse reactions to emtricitabine/tenofovir disoproxil fumarate should be reported to Macleods via email to uksafety@macleodspharma.com

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