tillomed

PrEP CHECKLIST FOR PRESCRIBERS
EMTRICITABINE/TENOFOVIR DISOPROXIL

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 PrEP indication for the individual who is about to start or is taking emtricitabine/tenofovir disoproxil for a PrEP indication:

Initial evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed negative Human Immunodeficiency Virus (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 gonorrhea
- ☐ If applicable, evaluated risk/benefit for women who may be pregnant or may want to become pregnant
- ☐ Performed Hepatitis B Virus (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>

  Not recommended for use in individuals under the age of 18 years with renal impairment
- ☐ 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.

Counseling

- ☐ 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 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 gonorrhea, that can facilitate HIV-1 transmission
- ☐ Discussed known safety risks with use of emtricitabine/tenofovir disoproxil 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
- ☐ Discontinued emtricitabine/tenofovir disoproxil for PrEP if seroconversion has occurred
- ☐ Performed screening for STIs, such as syphilis and gonorrhea

  Identified potential adverse reactions
- ☐ Performed renal monitoring as recommended

  In individuals without renal risk factors, renal function (CrCl 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:_____

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance: Website: www.hpra.ie

Adverse reactions/events should also be reported to the Tillomed Pharmacovigilance department at PVUK@tillomed.com.

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