✔ CHECKLIST FOR PRESCRIBERS

Initiation of Truvada® (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 Truvada® for a Pre-exposure Prophylaxis (PrEP) indication for the individual who is about to start or is taking Truvada® for a PrEP indication:

Lab Tests/Evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed negative HIV-1 test immediately prior to initiating Truvada® 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
  Truvada® is not recommended for use in HIV-1-uninfected adults with CrCl <60 mL/min. Truvada® should only be used in individuals with CrCl <80 mL/min if the potential benefits are considered to outweigh the potential risks.

  Uninfected adolescents
  Truvada® for PrEP should not be used in adolescents with renal impairment (i.e. creatinine clearance <90 mL/min/1.73 m^2).
- ☐ 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.
- ☐ Confirmed that the individual at risk is not taking other HIV-1 or HBV medications

Counselling

- ☐ Counselled that Truvada® 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 Truvada®
- ☐ 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 Truvada® for a PrEP indication to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing Truvada® 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 Truvada® for a PrEP indication
- ☐ Reviewed the document 'Important Information About Truvada® to Reduce the Risk of Getting Human Immunodeficiency Virus (HIV) Infection' with the individual

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 Truvada®
- ☐ Discontinued Truvada® for PrEP if seroconversion has occurred
- ☐ Performed screening for STIs, such as syphilis and gonorrhoea
- ☐ Identified potential adverse reactions
- ☐ Performed renal monitoring as recommended

  Uninfected adults
  If CrCl is decreased to <60 mL/min or serum phosphate is <1.5 mg/dL (0.48 mmol/L) in any individual receiving Truvada® for PrEP, renal function should be re-evaluated within 1 week, including measurements of blood glucose, blood potassium and urine glucose concentrations. Consideration should also be given to interrupting treatment with Truvada® in individuals with CrCl decreased to <60 mL/min or decreases in serum phosphate to <1.0 mg/dL (0.32 mmol/L). Interrupting use of Truvada® should also be considered in case of progressive decline of renal function when no other cause has been identified.

  Uninfected adolescents
  If serum phosphate is <3.0 mg/dL (0.96 mmol/L), renal function should be re-evaluated within one week, including measurements of blood glucose, blood potassium and urine glucose. If renal abnormalities are suspected or detected then consultation with a nephrologist should be obtained to consider interruption of treatment. Interrupting Truvada® should also be considered in case of progressive decline of renal function when no other cause has been identified.
- ☐ 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

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