

# ✓ CHECKLIST FOR PRESCRIBERS

Initiation and follow up 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:

## Initial 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

CrCl >80 mL/min. If CrCl <80 mL/min, use only if benefit outweighs risk. Not recommended if CrCl <60 mL/min.

### Uninfected adolescents

Should not be used if CrCl <90 mL/min/1.73 m<sup>2</sup>.

- 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 Truvada® and nephrotoxic agents is unavoidable, renal function should be monitored weekly.

## Counselling

- Counselling 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
- 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 Truvada®
- 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 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
- 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 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

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 and adolescents

Please refer to Safety leaflet for prescribers, section "Truvada® 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