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 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

- 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; a combined antigen/antibody test should be used.

☐ 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) is ≥ 80 mL/min

☐ Periodically during treatment confirmed CrCl is ≥ 60 mL/min and serum phosphate is ≥ 1.5 mg/dL (0.48 mmol/L)

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

☐ Confirmed that the individual at risk is not taking other HIV-1 or HBV medications

Counselling

☐ 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

☐ Counselled on the importance of adherence to dosing schedule

☐ 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

☐ Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)

☐ Discussed the importance of screening for sexually transmitted infections (STIs), such as syphilis and gonorrhoea, that can facilitate HIV-1 transmission

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- ☐ 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 a copy of the document titled 'Important information about Emtricitabine/Tenofovir disporoxil to Reduce the Risk of Getting Human Immunodeficiency Virus (HIV) infection' and a copy of the PrEP Patient Reminder Card to the individual

Follow Up

- ☐ Recorded next follow up appointment and HIV-1 screening test dates in the Reminder card and handed this out to the individual
- ☐ Provided a copy of the document titled "Important Information About Emtricitabine/Tenofovir Disoproxil to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection" and the Patient Reminder Card to the individual
- ☐ 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

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- ☐ 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

Reporter signature: _____ Print name: _____ Date: _____

Further copies of this educational material is available upon request from info.uk@mylan.co.uk

Reporting of side effects - Healthcare providers are asked to report any suspected adverse reactions. For any side effects please report to theMedicines Authority at http://www.medicinesauthority.gov.mt/adrportal or to the localrepresentative of Mylan S.A.S. : V.J. Salomone Pharma Ltd., Upper Cross Road,Marsa MRS1542, Malta, Tel: +356 21 220 174 and 24hPV mobile +356 99644126.

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By reporting side effects you can help provide moreinformation on the safety of this medicine.