Checklist for Prescribers:

Initiation of Emtricitabine/ Tenofovir Disoproxil Fumarate 200 mg/300 mg for HIV-1 Pre-exposure Prophylaxis (PrEP)

Individual Label

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 HIV-1 pre-exposure prophylaxis (PrEP) for the adult or adolescent weighing at least 35 kg who is about to start or is taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP:

Lab Tests/Evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
  - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive)
- ☐ Performed HBV screening test
- ☐ Confirmed estimated creatinine clearance (CrCl) ≥60 mL/min prior to initiation and periodically during treatment
- ☐ On a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients before initiation of emtricitabine/tenofovir disoproxil fumarate and periodically while emtricitabine/tenofovir disoproxil fumarate is being used. In patients with chronic kidney disease, also assess serum phosphorus. If a decrease in estimated CrCl is observed in uninfected individuals while using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate potential causes and re-assess potential risks and benefits of continued use
- ☐ Confirmed that the uninfected at-risk individual is not taking other HIV-1 medications or HBV medications
- ☐ Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

Counseling/Follow-up

- ☐ Discussed known safety risks with use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- ☐ Counseled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening tests (at least every 3 months), while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP to reconfirm HIV-1–negative status
  - Some individuals, such as adolescents, may benefit from more frequent visits and counseling
- ☐ Discussed the importance of discontinuing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- ☐ Counseled on the importance of adherence to daily dosing schedule
- ☐ Counseled that emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should be used only as part of a comprehensive prevention strategy
- ☐ 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 virologic suppression in partner(s) with HIV
- ☐ Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis, chlamydia, and gonorrhea, that can facilitate HIV-1 transmission
- ☐ Offered HBV vaccination as appropriate
- ☐ Provided education on where information about emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP can be accessed
- ☐ Discussed potential adverse reactions
- ☐ Reviewed the Emtricitabine/Tenofovir Disoproxil Fumarate Medication Guide with the uninfected at-risk individual