

Checklist for Prescribers: Initiation of Truvada® for 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 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 high risk evaluation of uninfected individual
- Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA 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 or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: TRUVADA for a PrEP indication 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. In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of TRUVADA and periodically while TRUVADA is being used. If a decrease in estimated CrCl is observed in uninfected individuals while using TRUVADA for a PrEP indication, evaluate potential causes and reassess potential risks and benefits of continued use
- Confirmed that the uninfected individual at high risk 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 TRUVADA for a PrEP indication
- 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 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
- Counseled on the importance of adherence to daily dosing schedule
- Counseled that TRUVADA for a PrEP indication 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 and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- Offered HBV vaccination as appropriate
- Provided education on where information about TRUVADA for a PrEP indication can be accessed
- Discussed potential adverse reactions
- Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk