## Current as of 6/1/2013 This document may not be part of the latest approved REMS. **Prescribers:**

**Individual Label** 

Initiation of TRUVADA® 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:	
☐ 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)	
☐ 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 (a least every 3 months), while taking TRUVADA for PrEP to confirm HIV-1 status	at
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	
$\square$ 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 an gonorrhea, that can facilitate HIV-1 transmission	d
☐ Performed HBV screening test. Offered HBV vaccination as appropriate	
☐ Confirmed creatinine clearance (CrCl) ≥60 mL/min. If a decrease in CrCl is observed in uninfected individuals while using TRUVADA for PrEP, evaluate potential causes and re-assess potential risks and benefits of continued use	
☐ Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or hepatitis B medication	S
☐ Provided education on where information about PrEP can be accessed	
☐ Discussed potential adverse events and side effects	
Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk	
☐ Evaluated risk/benefit for women who may be pregnant or may want to become pregnant	



