

Checklist for Prescribers

Initiating/Reauthorizing Truvada® for Pre-exposure Prophylaxis (PrEP)

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 every 6 months
- 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 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

Prescriber Patient Agreement form

Initiating/Reauthorizing Truvada® for Pre-exposure Prophylaxis (PrEP)

Please fax to: 1-866-839-2372

Healthcare Provider Agreement

By signing below, I signify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events.

Specifically, I attest to having done the following:

- Confirmed the negative HIV-1 status of this person prior to starting TRUVADA for a PrEP indication
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of TRUVADA for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TRUVADA for a PrEP indication
- Reviewed the TRUVADA Medication Guide with the HIV-negative person at high risk prior to prescribing Truvada for a PrEP indication
- Completed the items on the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

HIV-Negative Person Agreement

By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of Truvada to reduce the risk of getting HIV-1 infection, and I understand them clearly.

Specifically, I attest to the following:

- My healthcare provider talked with me about the importance of follow-up HIV-1 testing, and I agree to have repeat HIV-1 screening tests (at least every 3 months) as scheduled by my healthcare provider
- My healthcare provider talked with me about the safety risks involved with using Truvada to reduce the risk of getting HIV-1 infection
- My healthcare provider talked with me about a complete prevention strategy and always practicing safer sex by using condoms correctly
- I will talk with my healthcare provider if I have any questions
- I have read the Truvada Medication Guide

HIV-Negative Person's Signature

Date

Healthcare Provider's Signature

Date

Prior Authorization Request
Truvada® for PrEP
 Please fax to: 1-866-839-2372

Member Information	Prescriber Information
Member Name:	Prescriber Name:
Member ID:	Prescriber NPI:
Date of Birth: / /	Prescriber Address:
Member Address:	Office Phone:
Member Phone:	Office Fax:

Diagnosis	
<input type="checkbox"/> Pre-exposure prophylaxis (PrEP) of HIV	ICD-10 code:

PrEP Initiation <i>(Please provide copy of all laboratory reports listed below*)</i>
<input type="checkbox"/> Completed high risk evaluation of uninfected individual <input type="checkbox"/> Confirmed a negative HIV-1 test within the past two weeks* Date of last negative HIV test: / / <input type="checkbox"/> Performed HBV screening test every 6 months <input type="checkbox"/> Confirmed estimated creatinine clearance (CrCl) > 60 mL/min* <input type="checkbox"/> Confirmed that the uninfected individual at high risk is not taking other HIV medications or HBV medications <input type="checkbox"/> Evaluated risk/benefit for women who may be pregnant or may want to become pregnant <input type="checkbox"/> Completed agreement form with member

PrEP Reauthorization *(Please provide copy of all laboratory report)*

- | | |
|---|---|
| <input type="checkbox"/> Confirmed a negative HIV-1 status | Date of last negative HIV test: / / |
| <input type="checkbox"/> Confirmed negative HBV status every 6 months | |
| <input type="checkbox"/> Completed agreement form with member | |

I certify that, to the best of my knowledge, all information I have provided on this request is complete and factual.

Signature _____ Date _____