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
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

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<thead>
<tr>
<th>Member Name:</th>
<th>Prescriber Name:</th>
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<th>Date of Birth:</th>
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## Diagnosis

- [ ] Pre-exposure prophylaxis (PrEP) of HIV

  ICD-10 code: 

## PrEP Initiation

- [ ] Completed high risk evaluation of uninfected individual

- [ ] Confirmed a negative HIV-1 test within the past two weeks

  Date of last negative HIV test: / /

  *(Please provide copy of laboratory report)*

- [ ] Performed HBV screening test

- [ ] Confirmed estimated creatinine clearance (CrCl) > 60 mL/min

- [ ] Confirmed that the uninfected individual at high risk is not taking other HIV medications or HBV medications

- [ ] Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

- [ ] Completed agreement form with member

## PrEP Reauthorization

- [ ] Confirmed a negative HIV-1 status

  Date of last negative HIV test: / /

  *(Please provide copy of laboratory report)*

- [ ] Completed agreement form with member

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

Signature __________________________ Date __________________________

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Phone: 202-821-1127 Fax: 202-821-1098