This document contains copy for the creation of the REMS for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP HCP Website.

Revised: 05/18
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The information on this site is intended for audiences in the United States only. The content on this site may not apply to non-US audiences as regulatory control, legal requirements and/or medical practices may vary in other countries.

FTC/TDF Sponsor(s)
REMS-SSS-0036 05/18
**Global Right Rail Callouts**

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

This is a Risk Evaluation and Mitigation Strategy (REMS) Web site.
Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP—in combination with safer sex practices—can help reduce the risk of sexually acquired HIV-1 infection as part of a comprehensive HIV-1 prevention strategy in at-risk adults and adolescents weighing at least 35kg. Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP does not replace existing prophylaxis strategies.

Review factors that can help healthcare providers identify individuals at risk for sexually acquired HIV-1 infection and important prescribing considerations.

Report completion of training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

Participate in a Knowledge, Attitude, and Behavior (KAB) survey to assess the use and understanding of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

REMS Information
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

To help ensure that emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is prescribed and taken safely, emtricitabine/tenofovir disoproxil fumarate Sponsor(s) has worked with the FDA to develop materials for the REMS program to educate and inform healthcare providers and at-risk uninfected adults and adolescents weighing at least 35kg for acquiring HIV-1.

Access REMS resources >
| Slide 1 | Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP)  
Healthcare Provider Training |
|---|---|
| Slide 2 | **Pre-Exposure Prophylaxis (PrEP) Indication**  
- Emtricitabine/tenofovir disoproxil fumarate is indicated in combination with safer sex practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg. Individuals must have a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate.  
  - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting PrEP for at least one month and reconfirm HIV-1 status or use a test cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection |
| Slide 3 | **Factors to Help Identify Individuals At Risk**  
- Has partner known to be HIV-1 infected, or  
- Engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as:  
  - Inconsistent or no condom use  
  - Diagnosis of sexually transmitted infections  
  - Exchange of sex for commodities (such as money, shelter, food, or drugs)  
  - Use of illicit drugs or alcohol dependence  
  - Incarceration  
  - Partner(s) of unknown HIV-1 status with any of the factors listed above |
When Prescribing Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP, Healthcare Providers MUST:

- Use emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP only as part of a comprehensive prevention strategy that includes other prevention measures, such as safer sex practices, because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing acquisition of HIV-1 infection
- Counsel all uninfected individuals about safer sex practices that include consistent and correct use of condoms, knowledge of their HIV-1 status and that of their partner(s), the importance of virologic suppression in their partner(s) with HIV-1 and regular testing for other sexually transmitted infections that can facilitate HIV-1 transmission (such as syphilis, chlamydia, and gonorrhea)
- Inform uninfected individuals about and support their efforts in reducing sexual risk behavior
- Many HIV-1 tests, such as rapid tests, detect anti-HIV antibodies and may not identify HIV-1 during the acute stage of infection. Prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate seronegative individuals for current or recent signs or symptoms consistent with acute viral infections (e.g., fever, fatigue, myalgia, skin rash) and ask about potential exposure events (e.g., unprotected, or condom broke during, sex with an HIV-1 infected partner) that may have occurred within the last month
- If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting HIV-1 PrEP for at least one 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

The following points should also be considered when prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in adolescents:

- Use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP as part of a comprehensive HIV prevention strategy for adolescents should include consideration of the ability of the individual to understand the importance of adherence to daily dosing, the need for frequent HIV testing, the need for frequent sexually transmitted infection testing, and the continued risk of pregnancy
- In a clinical study in adolescents, the percentage of subjects with protective levels of drug declined markedly after subjects switched from monthly to quarterly visits, suggesting that adolescents may benefit from more frequent visits and counseling

BOXED WARNING

- Emtricitabine/tenofovir disoproxil fumarate used for a HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initial use and periodically (at least every 3 months) during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed.
Slide 7

**BOXED WARNING (Continued)**

- Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued emtricitabine/tenofovir disoproxil fumarate. Hepatic function should be monitored closely in HBV-infected patients who discontinue emtricitabine/tenofovir disoproxil fumarate. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Slide 8

**Why Use Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP?**

- By inhibiting HIV-1 from replicating as it enters the body, emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP works to prevent the virus from establishing permanent infection. However, emtricitabine/tenofovir disoproxil fumarate should not be seen as the first line of defense against HIV-1 infection.

- Because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1, emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP must be used in combination with a comprehensive prevention strategy that includes safer sex practices, such as regular and correct condom use, regular HIV testing for themselves (and their sexual partners), and other proven HIV prevention methods to safely and effectively reduce the risk of acquiring HIV-1 infection.
  - Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP must only be prescribed to uninfected individuals at risk who are confirmed to be HIV-1 negative.
  - Uninfected individuals who are prescribed emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should not miss any doses. Missing doses may increase the risk of acquiring HIV infection.

Slide 9

**Key Findings of the Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP Studies: The iPrEx Trial**

- In one clinical trial of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, emtricitabine/tenofovir disoproxil fumarate was shown to reduce the risk of HIV-1 acquisition by 42% for high risk adult men who have sex with men who also received comprehensive prevention services, including monthly HIV-1 testing, condom provision, counseling, and management of other sexually transmitted infections.

- In a post-hoc case control study of plasma and intracellular drug levels in about 10% of clinical trial subjects, risk reduction appeared to be the greatest in subjects with detectable intracellular tenofovir. Efficacy was therefore strongly correlated with adherence.

- Intensive risk reduction counseling was provided as part of the trial, and self-reported risk behavior among the subjects in this clinical trial declined overall during the trial, both in terms of decreases in the number of sexual partners and increases in condom use.
Key Findings of the Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP Studies: The Partners PrEP Trial

- In another clinical trial of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, emtricitabine/tenofovir disoproxil fumarate was shown to reduce HIV-1 acquisition by 75% in uninfected individuals in stable adult heterosexual serodiscordant relationships who also received comprehensive prevention services, including monthly HIV testing, evaluation of adherence, assessment of sexual behavior, and safety evaluations.

- In a post-hoc case control study of plasma drug levels in about 10% of study subjects, risk reduction appeared to be the greatest in subjects with detectable plasma tenofovir. Efficacy was therefore strongly correlated with adherence. Risk reduction increased further in subjects with detectable plasma tenofovir.

Important Safety Information: Comprehensive Management to Reduce the Risk of Acquiring HIV-1 and Development of HIV-1 Resistance

- Use emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP only as part of a comprehensive prevention strategy that includes other prevention measures, such as safer sex practices, because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection.
  - Counsel uninfected individuals about safer sex practices that include consistent and correct use of condoms, knowledge of their HIV-1 status and that of their partner(s), the importance of virologic suppression in their partner(s) with HIV-1 and regular testing for other sexually transmitted infections that can facilitate HIV-1 transmission (such as syphilis, chlamydia and gonorrhea).
  - Inform uninfected individuals about and support their efforts in reducing sexual risk behavior.
Important Safety Information: Comprehensive Management to Reduce the Risk of Acquiring HIV-1 and Development of HIV-1 Resistance

- Use emtricitabine/tenofovir disoproxil fumarate to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-negative
  - HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only emtricitabine/tenofovir disoproxil fumarate, because emtricitabine/tenofovir disoproxil fumarate alone does not constitute a complete regimen for HIV-1 treatment; therefore, care should be taken to minimize drug exposure in HIV-infected individuals
- Many HIV-1 tests, such as rapid tests, detect anti-HIV antibodies and may not identify HIV-1 during the acute stage of infection. Prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate seronegative individuals for current or recent signs or symptoms consistent with acute viral infections (e.g., fever, fatigue, myalgia, skin rash, etc.) and ask about potential exposure events (e.g., unprotected, or condom broke during sex with an HIV-1 infected partner) that may have occurred within the last month

While using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, HIV-1 screening tests should be repeated at least every 3 months and upon diagnosis of any sexually transmitted infections. Some individuals, such as adolescents may benefit from more frequent visits and counseling
  - If a screening test indicates possible infection or symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection

Counsel uninfected individuals to strictly adhere to the recommended daily emtricitabine/tenofovir disoproxil fumarate dosing schedule. The effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 is strongly correlated with adherence, as demonstrated by measurable drug levels in clinical trials.
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**Important Safety Information: Additional Warnings and Precautions**

**New Onset or Worsening Renal Impairment**

- Can include acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia)
- Prior to initiating and during use of emtricitabine/tenofovir disoproxil fumarate, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients
- In patients with chronic kidney disease, also assess serum phosphorus

Slide 16

**Important Safety Information: Additional Warnings and Precautions**

**New Onset or Worsening Renal Impairment**

- Emtricitabine/tenofovir disoproxil fumarate should be avoided with concurrent or recent use of a nephrotoxic agent. Cases of acute renal failure after initiation of high-dose or multiple NSAIDs have been reported. Some required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered, if needed, in patients at risk for renal dysfunction
- Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is not recommended in uninfected individuals with an estimated CrCl below 60 mL/min
  - If a decrease in estimated CrCl is observed while using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate potential causes and re-assess potential risks and benefits of continued use

Slide 17

**Important Safety Information: Additional Warnings and Precautions**

**Lactic acidosis/severe hepatomegaly with steatosis:**

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity

**Bone effects**

- Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with tenofovir disoproxil fumarate. Consider assessment of BMD in individuals with a history of pathologic fracture or other risk factors for osteoporosis or bone loss
- Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at-risk patients
Important Safety Information: Additional Warnings and Precautions

Severe Acute Exacerbation of Hepatitis B in Patients with HBV Infection

• All patients should be tested for HBV infection before or when starting emtricitabine/tenofovir disoproxil fumarate
• HBV-uninfected individuals should be offered vaccination
• HBV infected individuals should be monitored closely with both clinical and laboratory follow-up for exacerbation of hepatitis B for at least several months after discontinuing emtricitabine/tenofovir disoproxil fumarate (see BOXED WARNING)

Coadministration with other products

• Do not use emtricitabine/tenofovir disoproxil fumarate with drugs containing emtricitabine, tenofovir disoproxil fumarate, or tenofovir alafenamide, with drugs containing lamivudine, or with adefovir dipivoxil

Important Safety Information: Use of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP in Specific Populations

Pregnancy

• There are no adequate and well controlled trials in pregnant women.
• Published studies indicate an increased risk of HIV-1 infection during pregnancy and an increased risk of mother to child transmission during acute HIV-1 infection. In women at risk of acquiring HIV-1, consideration should be given to methods to prevent acquisition of HIV, including continuing or initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, during pregnancy
• A pregnancy registry is available. Enroll pregnant women exposed to emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP by calling 1-800-258-4263

Lactation

• It is not known if the components of emtricitabine/tenofovir disoproxil fumarate affect milk production or have effects on the breastfed child
• In HIV-uninfected women, the developmental and health benefits of breastfeeding and the mother’s clinical need for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should be considered along with any potential adverse effects on the breastfed child from emtricitabine/tenofovir disoproxil fumarate and the risk of HIV-1 acquisition due to nonadherence and subsequent mother to child transmission
• Women should not breastfeed if acute HIV-1 infection is suspected because of the risk of HIV-1 transmission to the infant
### Important Safety Information: Use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in Specific Populations

#### Pediatrics
- Safety, adherence, and resistance were evaluated in a single-arm, open label clinical trial (ATN113) of 67 HIV-1 uninfected at-risk adolescent men who have sex with men received emtricitabine/tenofovir disoproxil fumarate once daily for HIV-1 PrEP
- In the ATN113 trial, HIV-1 seroconversion occurred in 3 subjects. Tenofovir diphosphate (DP) levels in dried blood spot assays indicate that these subjects had poor adherence
- Adherence to study drug, as demonstrated by tenofovir DP levels in dried blood spot assays, declined markedly after Week 12 once subjects switched from monthly to quarterly visits, suggesting that adolescents may benefit from more frequent visits and counseling

### Important Safety Information: Confirming and Regularly Reconfirming Negative HIV-1 Status
- Emtricitabine/tenofovir disoproxil fumarate should be used to reduce the risk of acquiring HIV-1 infection only in individuals confirmed to be HIV-1 negative
  - A negative HIV-1 status should be confirmed before prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
  - Individuals should be regularly tested (at least every 3 months) while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP to reconfirm that they are HIV-1 negative. Some individuals, such as, adolescents may benefit from more frequent visits and counseling
  - If a screening test indicates possible infection, or symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection
Important Safety Information: Confirming and Regularly Reconfirming Negative HIV Status

Potential for Resistance in Undetected Acute HIV-1 Infection

- It is important to be alert to the signs of potential acute HIV-1 infection when prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. These include fever, headache, fatigue, arthralgia, vomiting, myalgia, diarrhea, pharyngitis, rash, night sweats, and cervical and inguinal adenopathy.

- HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

  - Although emtricitabine/tenofovir disoproxil fumarate is active against HIV-1, emtricitabine/tenofovir disoproxil fumarate alone does not constitute a complete treatment regimen for HIV-1 infection.

  - HIV-1 infected patients taking emtricitabine/tenofovir disoproxil fumarate must take it with other antiretroviral agents to fully suppress virus replication and avoid the development of resistance.

Important Safety Information: Drug Interactions and Common Adverse Events

Drug Interactions

- Coadministration of emtricitabine/tenofovir disoproxil fumarate with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir.

- For further details about emtricitabine/tenofovir disoproxil fumarate drug interactions, please see the Prescribing Information [link to PDF of PI] for emtricitabine/tenofovir disoproxil fumarate.

Common Adverse Reactions

- In HIV-1 uninfected adults in HIV-1 PrEP trials, adverse reactions that were reported by more than 2% of emtricitabine/tenofovir disoproxil fumarate subjects and more frequently than by placebo subjects were headache, abdominal pain and decreased weight.
Additional Educational Materials
• Agreement Form for Initiating Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP)
  – Designed for prescribers to use with uninfected individuals to facilitate discussion of appropriate use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
  – Form covers safety risks associated with use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, the importance of adherence to the recommended daily dosing regimen, regular assessment of HIV-1 test results, and screening for sexually transmitted infections
• Checklist for Prescribers: Initiation of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP)
  – Checklist of key components for prescribers to consider before starting an uninfected individual on emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
  – Checklist items include confirming a negative HIV-1 test result, screening for signs or symptoms of acute HIV-1 infection, counseling on safety risks and importance of adherence, and other components to ensure a comprehensive prevention strategy
• Copies available from www.ftc-tdf-preprems.com or by filling out the postage paid, business reply card at the back of the Training Guide for Healthcare Providers

Additional Educational Materials
• Additional educational materials can be reviewed and downloaded at www.ftc-tdf-preprems.com
• Please confirm completion of training by going to www.ftc-tdf-preprems.com or by filling out the postage paid, business reply card at back of the Training Guide for Healthcare Providers
• A survey is being conducted to fulfill an FDA-required Risk Evaluation and Mitigation Strategy (REMS) program to assess prescribers’ knowledge regarding important safety information associated with the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. To participate, please go to www.ftc-tdf-preprems.com

Additional Educational Materials
• Important Safety Information for Adolescents Who Don’t Have HIV
  – Designed as an educational tool for HIV-1 uninfected adolescents
  – Contains similar information as the educational tool written for adults Important Safety Information for Adults Who Don’t Have HIV but written to be more easily understood by adolescents
  – Copies are available from www.ftc-tdf-preprems.com or by filling out business reply card at the back of the Training Guide for Healthcare Providers booklet
Post-training screen

Assess Your Knowledge of Emtricitabine/Tenofovir Disoproxil Fumarate for a HIV-1 PrEP

[Buttons]
Go to review questions [Advances to questions page/launches question 1]
No thanks [Advances to input screen for specialty/degree]

Report completion of training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
[link to UBC and external database to capture name, degree, address (street, city, state, zip) and specialty]

Participate in a knowledge, attitude, and behavior (KAB) survey to assess the use and understanding of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
[link to UBC for KAB pre-qualification page]

Question 1

Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP should be used only:

Correct answer: D

a) As part of a comprehensive HIV-1 prevention strategy that includes other preventive measures, since emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection
b) In individuals who have been counseled to strictly adhere to their emtricitabine/tenofovir disoproxil fumarate daily dosing schedule, since the effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence and measurable drug levels
c) In individuals who have a confirmed negative HIV-1 test prior to initiating and routinely while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
d) All of the above

Correct
Next
[Advances to next screen]

Incorrect. Please try again.
Try again
[Greys out selected wrong answer]
**Question 2**

**Which of the following statements is false?**

a) Emtricitabine/tenofovir disoproxil fumarate should be used for HIV-1 PrEP only in individuals confirmed to be HIV-1 negative

b) Emtricitabine/tenofovir disoproxil fumarate is indicated for HIV-1 pre-exposure prophylaxis to reduce the risk of acquiring HIV-1 infection through injection drug use

c) Women taking Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should not breastfeed their babies if acute HIV-1 infection is suspected

d) Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is not always effective in preventing HIV-1 infection

Correct answer: B

**Question 3**

**Which of the following items are not included on the Checklist for Prescribers for initiating Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP?**

a. Perform HBV screening test

b. Perform testing for TB

c. Confirm negative HIV-1 status of the individual

d. Confirm creatinine clearance is ≥60 mL/min

Correct answer: B
<table>
<thead>
<tr>
<th>Question 4</th>
<th>Hepatic function should be monitored closely in:</th>
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| Correct answer: A | a. HBV-infected patients who discontinue emtricitabine/tenofovir disoproxil fumarate  
b. All people taking emtricitabine/tenofovir disoproxil fumarate  
c. All people who discontinue emtricitabine/tenofovir disoproxil fumarate  
d. None of the above |

<table>
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<tr>
<th>Question 5</th>
<th>In clinical trials evaluating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, which of the following adverse reactions was not common?</th>
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| Correct answer: c | a) Abdominal pain  
b) Headache  
c) Dizziness  
d) Decreased weight |

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<tr>
<th>Question 6</th>
<th>Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is indicated only for:</th>
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</table>
| Correct answer: D | a) Men who are at risk for sexually acquired HIV-1 infection  
b) Adults and adolescents weighing at least 35 kg who are at risk of acquiring HIV-1 infection by any means  
c) Adults and adolescents weighing at least 35 kg who are at risk of acquiring HIV-1 infection through injection drug use  
d) Adults and adolescents weighing at least 35 kg who are at risk for sexually acquired HIV-1 infection |
The Agreement Form for Initiating Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP) provides which of the following information:

a. A list of activities that put individuals at risk for sexually acquired HIV-1 infection

b. A confirmation that the prescriber has discussed the risks and benefits of using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP with the uninfected individual

c. A signature from the individual asserting that the prescriber has explained the risks and benefits of taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, including the need for adherence and a comprehensive prevention strategy, which includes safer sex practices

d. All of the above
To help emtricitabine/tenofovir disoproxil fumarate Sponsor(s) and the FDA understand who has viewed this training, please tell us the following

Your Specialty:

[drop down menu]
Internal medicine
Family practice
General medicine
Infectious diseases
Obstetrics/gynecology
Addiction medicine
Other

Profession:

[drop down menu]
MD
PA
NP
Other

Zip Code: [insert box to capture 5 digit zip code]

[Buttons]
Submit [Advances to thank you screen]
No thanks [Closes div layer]

[one time error state if user misses a field on “Submit” only]
Please provide this information.

Report completion of training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
[link to UBC and external database to capture name, degree, address (street, city, state, zip) and specialty]

Participate in a Knowledge, Attitude, and Behavior (KAB) survey to assess the use and understanding of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
[link to UBC for KAB pre-qualification page]

Thank you [Closes div layer]
### 1.1. About Emtricitabine/Tenofovir Disoproxil Fumarate for PrEP

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<tr>
<th>Area on page</th>
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<tbody>
<tr>
<td><strong>Headline</strong></td>
<td>About emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
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</tbody>
</table>

Emtricitabine/tenofovir disoproxil fumarate is indicated in combination with safer sex practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg at risk. The following factors may help to identify individuals at risk:

- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as:
  - Inconsistent or no condom use
  - Diagnosis of sexually transmitted infections
  - Exchange of sex for commodities (such as money, shelter, food, or drugs)
  - Use of illicit drugs, alcohol dependence
  - Incarceration
  - Partner(s) of unknown HIV-1 status with any of the factors listed above
When prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 pre-exposure prophylaxis, healthcare providers must:

- Prescribe emtricitabine/tenofovir disoproxil fumarate as part of a comprehensive prevention strategy because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection.
- Counsel all uninfected individuals to strictly adhere to the recommended emtricitabine/tenofovir disoproxil fumarate daily dosing schedule because the effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 infection was strongly correlated with adherence and measurable drug levels.
- Confirm 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) exposures are 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.
- Screen for HIV-1 infection at least once every 3 months while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.
- Be sure to not prescribe emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV-1 infection are present.

The following points should be also considered when prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in adolescents:

- Use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP as part of a comprehensive HIV prevention strategy for adolescents should include consideration of the ability of the individual to understand the importance of adherence to daily dosing, the need for frequent HIV testing, the need for frequent sexually transmitted infection testing, and the continued risk of pregnancy.
- In a clinical study in adolescents, the percentage of subjects with protective levels of drug declined markedly after subjects switched from monthly to quarterly visits suggesting that adolescents may benefit from more frequent visits and counseling.
<table>
<thead>
<tr>
<th>H2</th>
<th><strong>Mechanism of action for HIV-1 pre-exposure prophylaxis</strong></th>
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<tbody>
<tr>
<td>Copy</td>
<td>By inhibiting HIV-1 from replicating as it enters the body, emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP helps prevent the virus from establishing permanent infection. Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP <strong>does not</strong> replace existing HIV-1 prevention strategies.</td>
</tr>
<tr>
<td>Next page callout</td>
<td>Next: Comprehensive Management</td>
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1.2. Comprehensive Management

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<tr>
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<td>Headline</td>
<td>Comprehensive Management</td>
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</table>
Use emtricitabine/tenofovir disoproxil fumarate for HIV-1 pre-exposure prophylaxis only as part of a comprehensive prevention strategy that includes other prevention measures, such as safer sex practices, because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection.

- Counsel uninfected individuals about safer sex practices that include consistent and correct use of condoms, limiting the number of sexual partners, knowledge of their HIV-1 status and that of their partner(s), the importance of virologic suppression in their partner(s) with HIV-1 and regular testing for other sexually transmitted infections that can facilitate HIV-1 transmission (such as syphilis, chlamydia and gonorrhea).
- Inform uninfected individuals about and support their efforts in reducing sexual risk behavior.

Use emtricitabine/tenofovir disoproxil fumarate to reduce the risk of acquiring HIV-1 infection only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only emtricitabine/tenofovir disoproxil fumarate, because emtricitabine/tenofovir disoproxil fumarate alone does not constitute a complete treatment regimen for HIV-1 treatment; therefore, care should be taken to minimize drug exposure in HIV-1 infected individuals.

- Evaluate for signs or symptoms of acute HIV-1 infection prior to prescribing and while taking emtricitabine/tenofovir disoproxil fumarate.
- You must confirm a negative HIV-1 test immediately prior to prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting emtricitabine/tenofovir disoproxil fumarate for at least 1 month and reconfirm HIV-1 negative 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.
- Screen for HIV-1 infection at least once every 3 months while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Some individuals, such as, adolescents may benefit from more frequent visits and counseling.
- If a screening test indicates possible infection, or symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection.

Counsel uninfected individuals to strictly adhere to the recommended emtricitabine/tenofovir disoproxil fumarate daily dosing schedule. The effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence and measurable drug levels.
| **Bold copy** | **It’s important to remember that emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is contraindicated in individuals with unknown or positive HIV-1 status. Emtricitabine/tenofovir disoproxil fumarate should only be used in HIV-1 infected patients in combination with other antiretroviral agents.** |
| **Copy** | **Access tools that can help you manage and counsel individuals on the correct and safe use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.**  
**Checklist for Prescribers >**  
**Agreement form >** |
## 2.1. Checklist for Prescribers

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<tr>
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<tr>
<td>Headline</td>
<td>Checklist for Prescribers</td>
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<tr>
<td>Copy</td>
<td>Before prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, it’s important that you complete the Checklist for Prescribers: Initiation of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-Exposure Prophylaxis (PrEP) with uninfected individuals and file in the individual’s medical record. On each visit with an uninfected individual, complete the following steps:</td>
</tr>
</tbody>
</table>

- Complete risk evaluation of uninfected individual
- Confirm 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 one 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)  
- Discuss known safety risks with use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Counsel 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 status.  
  - Some individuals, such as, adolescents may benefit from more frequent visits and counseling  
- Discuss 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  
- Counsel on the importance of adherence to daily dosing schedule  
- Counsel that emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should be used only as part of a comprehensive prevention strategy  
- Educate on practicing safer sex consistently and using condoms correctly  
- Discuss the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)  
- Discuss the importance of virologic suppression in partner(s) with HIV  
- Discuss the importance of and perform screening for sexually transmitted infections (STIs), such as syphilis, chlamydia and gonorrhea, that can facilitate HIV-1 transmission |
- Perform HBV screening test. Offer HBV vaccination as appropriate
- 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
- Confirm that the uninfected individual at risk is not taking other HIV-1 medications or hepatitis B medications
- Provide education on where information about emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP can be accessed
- Discuss potential adverse events
- Review the emtricitabine/tenofovir disoproxil fumarate Medication Guide with the uninfected individual at risk
- Evaluate risk/benefit for women who may be pregnant or may want to become pregnant
### 2.2. Agreement Form

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<tr>
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<td>Headline</td>
<td>Agreement Form</td>
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<tr>
<td>Copy</td>
<td>As part of helping uninfected individuals understand the commitment in taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, the Agreement Form for Initiating Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP) has been created. It’s important that you use the form to review the factors that may help to identify uninfected individuals at risk. These include:</td>
</tr>
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</table>
| Copy         | ▪ Has partner(s) known to be HIV-1 infected, or  
▪ Engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as:  
  - Inconsistent or no condom use  
  - Diagnosis of sexually transmitted infections  
  - Exchange of sex for commodities (such as money, shelter, food, or drugs)  
  - Use of illicit drugs, alcohol dependence  
  - Incarceration  
  - Partner(s) of unknown HIV-1 status with any of the factors listed above |
| Copy         | After you review the risks and benefits with the individual, you must both sign and date the form and file in the individual’s medical record. This will help to reinforce the importance of understanding the risks involved with emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Download a printable version of the Agreement Form. |
| Next page callout | Next: REMS Materials |

Reference ID: 4262803
3.1. REMS Materials

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<td>Headline</td>
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<tr>
<td>Copy</td>
<td>On this page, you’ll find downloadable resources for you and uninfected individuals. You will need Adobe Acrobat installed on your computer to view these resources. If you do not have it and would like to download it, please click here.</td>
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</table>

H3 | Dear Health Care Provider Letter

Download box

<table>
<thead>
<tr>
<th></th>
<th>Information for healthcare providers on the new emtricitabine/tenofovir disoproxil fumarate indication for HIV-1 pre-exposure prophylaxis (PrEP)</th>
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H3 | Training Guide for Healthcare Providers

Download box

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<thead>
<tr>
<th></th>
<th>A comprehensive overview of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</th>
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H3 | Important Safety Information for Healthcare Providers

Download box

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<th>Important safety information about emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</th>
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<td>Download</td>
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<td></td>
<td>[Links to PDF download]</td>
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</table>

H3 | Safety Information Fact Sheet

Download box

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<tr>
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<th>A detailed overview of the safety information for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</th>
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<td>Download</td>
<td>Download</td>
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H3 | Prescriber-Individual Agreement Form
<table>
<thead>
<tr>
<th>Download box</th>
<th>Form that should be reviewed with an individual considering/taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</th>
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</thead>
<tbody>
<tr>
<td>H3</td>
<td>Checklist for Prescribers</td>
</tr>
<tr>
<td>Download box</td>
<td>Tool for facilitating appropriate prescribing of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
</tr>
<tr>
<td>H3</td>
<td>Medication Guide</td>
</tr>
<tr>
<td>Download box</td>
<td>A comprehensive guide for uninfected individuals getting started on emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
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<tr>
<td>H3</td>
<td>Important Safety Information for Adults Who Don’t Have HIV</td>
</tr>
<tr>
<td>Download box</td>
<td>An easy-to-understand guide on the most important safety information about emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
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<tr>
<td>H3</td>
<td>Important Safety Information for Adolescents Who Don’t Have HIV</td>
</tr>
<tr>
<td>Download box</td>
<td>An easy-to-understand guide for adolescents on the most important safety information about emtricitabine/tenofovir disoproxil fumarate for a HIV-1 PrEP</td>
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<tr>
<td>H3</td>
<td>Prescribing Information</td>
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<tr>
<td>Download box</td>
<td>Prescribing Information for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
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Next page callout | Next: Post-Training Review Questions
### 3.2. Post-Training Review Questions

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<tbody>
<tr>
<td>Headline</td>
<td><strong>Post-Training Review Questions</strong></td>
</tr>
<tr>
<td>Copy</td>
<td>If you are a healthcare provider considering prescribing emtricitabine/tenofovir disoproxil fumarate for a HIV-1 PrEP, assess your knowledge about the safe use of emtricitabine/tenofovir disoproxil fumarate for a HIV-1 PrEP.</td>
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<tr>
<td>Copy</td>
<td><strong>Go to review questions</strong></td>
</tr>
<tr>
<td></td>
<td>Report completion of training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
</tr>
<tr>
<td></td>
<td>Participate in a knowledge, attitude, and behavior (KAB) survey to assess the use and understanding of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP</td>
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<tr>
<td>Copy</td>
<td>The information on this site is intended for residents of the United States.</td>
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<td>Buttons</td>
<td>OK [/Continues to site]</td>
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</tbody>
</table>

Reference ID: 4262803
5.0 Site Map

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<tr>
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<tbody>
<tr>
<td>Headline</td>
<td>Site Map</td>
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<td>Copy</td>
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</tbody>
</table>

**Home**

**Prophylaxis Therapy**
- Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Comprehensive Management

**Starting Individuals**
- Checklist for Prescribers
- Agreement Form

**Support**
- REMS Materials
- Post-Training Review Questions

6.0 Report completion of training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
[link to UBC and external database to capture name, degree, address (street, city, state, zip) and specialty]
https://itookthetraining.com/#Home/!Prescriber

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<td>Emtricitabine/tenofovir disoproxil fumarate Prescriber Training</td>
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<tr>
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<td>Have you completed the training for emtricitabine/tenofovir disoproxil fumarate for a HIV-1 PrEP?</td>
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<tr>
<td></td>
<td>Yes</td>
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<td></td>
<td>No</td>
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</table>

[If no, 6.1. If yes, 6.2]
[6.1-If no]:

All prescribers of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP are encouraged to review the training material available at www.ftc-tdf-preprems.com. After reviewing material, please return to this site to acknowledge completion of training.

[6.2- If yes]:

Medical Specialty: 

Degree: 

Prescriber First Name: 

Prescriber Middle Name: 

Prescriber Last Name: 

Street Address: 

City: 

State: 

Zip: 

7.0 Participate in a Knowledge, Attitude, and Behavior (KAB) survey to assess the use and understanding of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP

Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP Pre-registration

Thank you for your interest in the emtricitabine/tenofovir disoproxil fumarate for HIV-1 Pre-Exposure Prophylaxis (PrEP) survey! Please click the button that best describes you.

Please click the button that best describes you.

I am an HIV-1 Uninfected Individual   I am a Healthcare Provider

7.1 HIV-1 Uninfected Individual

Please answer the following questions to determine if you pre-qualify to take the emtricitabine/tenofovir disoproxil fumarate survey. The emtricitabine/tenofovir disoproxil fumarate survey will help the manufacturers of this medicine know if HIV-1 uninfected individuals understand important information about taking emtricitabine/tenofovir disoproxil fumarate. If you pre-qualify, we will ask for your contact information so that we can provide you with additional information about how to participate in the emtricitabine/tenofovir disoproxil fumarate survey. Participation is voluntary and the information you provide will be kept confidential. Your contact information will be stored securely and will not be shared with any third parties or with emtricitabine/tenofovir disoproxil fumarate Sponsor(s), the manufacturers of emtricitabine/tenofovir disoproxil fumarate.
The questions below are not part of the emtricitabine/tenofovir disoproxil fumarate survey. The emtricitabine/tenofovir disoproxil fumarate survey will take approximately 20 minutes and will ask questions about important safety information about emtricitabine/tenofovir disoproxil fumarate. You will receive a $25 gift card if you qualify for and complete the emtricitabine/tenofovir disoproxil fumarate survey. If you do not qualify for the emtricitabine/tenofovir disoproxil fumarate survey or if you do not complete the emtricitabine/tenofovir disoproxil fumarate survey, you will not receive the $25 gift card. You may not register to take this survey twice. If you qualify and take the survey more than once, you will only receive one $25 gift card. Please note, only residents of the United States may participate in the survey.

If you would like to see if you pre-qualify to participate in the emtricitabine/tenofovir disoproxil fumarate survey, please answer the following questions.

1. Are you at least 18 years old?
   ● Yes
   ● No

2. Are you a resident of the United States?
   ● Yes
   ● No

3. Are you currently taking emtricitabine/tenofovir disoproxil fumarate to prevent getting infected with HIV-1?
   ● Yes
   ● No

[If no to any one question]

Thank you for your interest in the emtricitabine/tenofovir disoproxil fumarate survey. Unfortunately, based on your answers you do not pre-qualify to participate in the emtricitabine/tenofovir disoproxil fumarate survey.

If yes to all:

First Name: __________________ Last Name: __________________

Please select your preferred method of contact: __________________

Please select a secondary method of contact: __________________

7.2 I am a Healthcare Provider
If you would like to see if you pre-qualify to participate in the emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP survey, please answer the following questions.

1. Have you prescribed emtricitabine/tenofovir disoproxil fumarate for any indication (e.g., for treatment of HIV-1 and/or for HIV-1 PrEP)?
   - Yes
   - No

2. Are you a resident of the United States?
   - Yes
   - No

[If no]
Thank you for your interest in the emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP survey. Unfortunately, based on your answer you do not pre-qualify to participate in the emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP survey.

[If yes]
Thank you for your interest in the emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP survey. At the end of this pre-qualification process, you will have the opportunity to go directly to the emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP KAB website and complete the survey. If you qualify and you complete the full emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP survey, you will receive a $125 honorarium for your time. Your contact information will be stored securely and will not be shared with any third parties or with emtricitabine/tenofovir disoproxil fumarate Sponsor(s), the manufacturers of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

We would like to collect your contact information for our records before you leave the pre-qualification website. Please provide your contact information below.

*Indicates required field.

First Name: __________________ Last Name: __________________
Address 1: __________________
Address 2: __________________
City: __________________
State: __________________
Zip: __________________
Telephone: __________________
Email: __________________

Submit