

Agreement Form

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

Individual Label

Instructions: Review form with an HIV-negative person who is about to start or is taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP at each visit. File form in the person's medical record.

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 in at-risk adults and adolescents weighing at least 35 kg. Individuals must have 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 cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection

The following factors may help to identify at-risk individuals:

- 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

Healthcare Provider Agreement

By signing below, I signify my understanding of the risks and benefits of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP 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 emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of virologic suppression in their partner(s) with HIV
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, noting that some individuals, such as adolescents, may benefit from more frequent visits and counseling
- Reviewed the emtricitabine/tenofovir disoproxil fumarate Medication Guide with the HIV-negative person at risk prior to prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Completed the items on the Checklist for Prescribers: Initiation of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP)

Healthcare Provider's Signature

Date

HIV-Negative Person Agreement

By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of emtricitabine/tenofovir disoproxil fumarate 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 emtricitabine/tenofovir disoproxil fumarate 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 emtricitabine/tenofovir disoproxil fumarate Medication Guide

HIV-Negative Person's Signature

Date