Agreement Form for Initiating [Pr]Mylan-Emtricitabine/Tenofovir Disoproxil for Pre-exposure Prophylaxis (PrEP) in adults at high risk of HIV-1 infection

Instructions: Please review this form at each visit with a patient who is planning to start or is already taking Mylan-Emtricitabine/Tenofovir Disoproxil for a PrEP indication. A copy of this form should be retained in the patient's medical record.

Mylan-Emtricitabine/Tenofovir Disoproxil is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

When considering Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP, the following factors may help to identify individuals at high risk:

- has partner(s) known to be HIV-1 infected, or
- engages in sexual activity within a high prevalence area or social network and one or more of the following:
    - inconsistent or no condom use
    - diagnosis of sexually transmitted infections
    - exchange of sex for commodities (such as money, food, shelter, or drugs)
    - use of illicit drugs or alcohol dependence
    - incarceration
    - partner(s) of unknown HIV-1 status with any of the factors listed above

Acknowledgement by Healthcare Provider

I hereby acknowledge that I have reviewed the Mylan-Emtricitabine/Tenofovir Disoproxil Product Monograph and understand the risks and benefits of use for the PrEP indication. I further acknowledge that I have communicated the risks of PrEP use to the patient and have provided education on risk reduction. By my signature below, I confirm that I have:

- prescribed Mylan-Emtricitabine/Tenofovir Disoproxil as part of a comprehensive prevention strategy because Mylan-Emtricitabine/Tenofovir Disoproxil is not always effective in preventing the acquisition of HIV-1 infection;
- counselled patient to strictly adhere to the recommended Mylan-Emtricitabine/Tenofovir Disoproxil dosing schedule because the effectiveness of Mylan-Emtricitabine/Tenofovir Disoproxil in reducing the risk of acquiring HIV-1 is strongly correlated with adherence;
- confirmed a negative HIV-1 test immediately prior to initiating Mylan-Emtricitabine/Tenofovir Disoproxil for a PrEP indication. If clinical symptoms consistent with acute viral infection were present and recent (<1 month) exposures were suspected, delayed starting PrEP for at least one month and reconfirmed HIV-1 status; and

- relayed to the patient the importance of regular HIV-1 testing, at least once every 3 months, while taking Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP.

I further acknowledge that I reviewed the *Mylan-Emtricitabine/Tenofovir Disoproxil Uninfected Patient Safety Brochure* with the patient and completed the items on the *Checklist for Prescribers: Initiation of Mylan-Emtricitabine/Tenofovir Disoproxil for Pre-Exposure Prophylaxis (PrEP)*, prior to prescribing Mylan-Emtricitabine/Tenofovir Disoproxil to the patient for PrEP.

Acknowledgement by HIV-Negative Patient

I hereby acknowledge that I have been counseled by my healthcare provider about the benefits and risks of use of Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP and I understand them clearly. Specifically, I hereby acknowledge that my healthcare provider explained to me:

- the importance of a comprehensive prevention strategy, such as condom use, because Mylan-Emtricitabine/Tenofovir Disoproxil is not always effective in preventing the acquisition of HIV-1 infection;
- the importance of adherence to the recommended dosing schedule; and
- the requirement to be screened for HIV-1 infection at least once every 3 months while taking Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP.

I also acknowledge that I have read the *Mylan-Emtricitabine/Tenofovir Disoproxil Uninfected Patient Safety Brochure* and will talk to my healthcare provider if I have any questions.

Please consult the Consumer Information section of the Product Monograph for information on warnings, precautions and side effects.

_____	_____	_____	_____
Healthcare Provider's Signature	*Date*	*Patient's Signature*	*Date*

Mylan-Emtricitabine/Tenofovir Disoproxil is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

Consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00048031.PDF for more information about conditions of clinical use, contraindications, warnings, precautions, adverse reactions, interactions and dosing. The Product Monograph is also available by calling 1 844 596-9526.