Checklist for Prescribers:

Initiation of PrTeva-Emtricitabine/Tenofovir for Pre-exposure Prophylaxis (PrEP) in Adults at High Risk of HIV-1 Infection

This material was developed by Teva Canada Limited, as part of the risk minimization plan for Teva-Emtricitabine/Tenofovir. This material is not intended for promotional use.

Instructions:

Complete this checklist at each visit and file in individual's medical record.

I have completed the following prior to prescribing TEVA-EMTRICITABINE/TENOFOVIR for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication:

LAB TESTS / EVALUATION

- ☐ Completed high-risk evaluation of uninfected individual
  - When considering TEVA-EMTRICITABINE/TENOFOVIR 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
- ☐ Confirmed a negative HIV-1 test immediately prior to initiating TEVA-EMTRICITABINE/TENOFOVIR 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 Health Canada as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: TEVA-EMTRICITABINE /TENOFOVIR is contraindicated for use as PrEP in individuals with unknown HIV-1 status or positive HIV-1 status)
- ☐ Tested for the presence of hepatitis B virus (HBV)
- ☐ Confirmed creatinine clearance (CrCl) > 60 mL/min prior to initiation and periodically during treatment. In patients at risk for renal dysfunction, assess calculated CrCl, serum phosphorus, urine glucose and urine protein before initiation of TEVA-EMTRICITABINE/TENOFOVIR and periodically during TEVA-EMTRICITABINE/TENOFOVIR therapy. If a decrease in CrCl is observed in uninfected individuals while using TEVA-EMTRICITABINE/TENOFOVIR for PrEP, evaluate potential causes and re-assess 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 TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication
- ☐ Counseled on the importance of regular HIV-1 screening tests (at least every 3 months), while taking TEVA-EMTRICITABINE/TENOFOVIR for PrEP to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing EMTRICIBATINE/TENOFOVIR for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- ☐ Counseled on the importance of strict adherence to daily dosing schedule
- ☐ Counseled that TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication should be used only as part of a comprehensive prevention strategy
- ☐ Educated on safer sex practices that include consistent and correct use of condoms
- ☐ 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 regular screening for other sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- ☐ Provided education on where information about TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication can be accessed
- ☐ Discussed potential adverse reactions
- ☐ Reviewed the TEVA-EMTRICITABINE/TENOFOVIR ***Risk minimization tool for individuals before HIV-1 exposure and at risk of infection – Important safety information***

Healthcare Provider's Signature	Date	HIV-Negative Person's Signature	Date

TEVA-EMTRICITABINE/TENOFOVIR 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.

Consult the product monograph https://www.tevacanada.com/globalassets/canada-ph2/product-monographs/emtricitabine-tenofovir-tabs-200mg-300mg-teva-pm-apr11_2019-full-indication-wis-eng.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use.

The product monograph is also available by calling Teva Canada at 1-855-223-6838.

Reference: 1. TEVA-EMTRICITABINE/TENOFOVIR Product Monograph. Teva Canada Limited. April 11, 2019.