Important Information for Prescribers About TRUVADA® for a Pre-exposure Prophylaxis (PrEP) Indication

TRUVADA® (emtricitabine/tenofovir disoproxil fumarate) is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.

BOXED WARNING SPECIFIC FOR USING TRUVADA FOR A PrEP INDICATION:
TRUVADA used for a PrEP indication must only be prescribed to individuals confirmed to be HIV-1 negative immediately prior to initiating and periodically (at least every 3 months) during use. Drug-resistant HIV-1 variants have been identified with the use of TRUVADA for a PrEP indication following undetected acute HIV-1 infection. Do not initiate TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

Key Safety Information to Communicate Regarding the Use of TRUVADA for a PrEP Indication:

1. Risk of Development of Drug-Resistant HIV-1 Variants in Undiagnosed HIV-1–Infected Individuals
   - HIV-1 variants with resistance have emerged in individuals taking TRUVADA for a PrEP indication with undetected acute HIV-1 infection
   - You must confirm a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication. If clinical signs or symptoms consistent with acute viral infection are present and recent (<1 month) exposures are 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
   - Screen for HIV-1 infection at least once every 3 months while taking TRUVADA for a PrEP indication. If symptoms consistent with acute HIV-1 infection develop following a potential exposure event, PrEP should be discontinued until negative infection status is confirmed using a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
     - TRUVADA for a PrEP indication is contraindicated in individuals with unknown or HIV-1–positive status
     - Do not prescribe TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed
     - HIV-1–infected patients must take TRUVADA in combination with other antiretroviral agents to fully suppress virus replication and avoid the development of resistance

2. Only Use TRUVADA for a PrEP Indication as Part of a Comprehensive Prevention Strategy
   - TRUVADA for a PrEP indication does not replace other HIV-1 infection prevention measures, including safer sex practices and correct and consistent condom use
   - Clinical trials included comprehensive prevention counseling, screening for and treatment of other sexually transmitted infections, and strong emphasis regarding consistent use of condoms and other safer sex practices

3. The Importance of Strict Adherence to the Recommended Dosing Regimen
   - The effectiveness of TRUVADA for a PrEP indication in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence and measurable drug levels
   - All uninfected individuals at high risk taking TRUVADA for a PrEP indication must be counseled to strictly adhere to the recommended daily dosing schedule to reduce the risk of acquiring HIV-1 infection

For more information about TRUVADA and its indication for PrEP, please see the Prescribing Information, including the BOXED WARNING, and the Medication Guide. For more information about the REMS program for TRUVADA for a PrEP indication, please log on to www.TRUVADAprepregs.com. You may also obtain additional information and educational materials about the use of TRUVADA for a PrEP indication at 1-800-445-3235.