Box 3: Important Clinical Considerations When Prescribing TDF/FTC as PrEP

☑ If the patient has chronic active hepatitis B virus (HBV):
  • Both tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) are active against HBV.
  • For more information, see AASLD guidelines for treatment of chronic hepatitis B.
  • TDF is approved by the U.S. Food and Drug Administration (FDA) for the treatment of HBV, and combination TDF/FTC used daily may be used as pre-exposure prophylaxis (PrEP) and as concomitant HBV treatment.*
  • Tenofovir alafenamide/emtricitabine (TAF/FTC) can be considered as an alternative regimen for HBV treatment and HIV prevention in men who have sex with men (MSM) and in transgender women, although it is not yet FDA-approved for use as PrEP. TAF has not yet been studied in other populations as PrEP.
  • Continuation of TDF or TDF/FTC or initiation of TAF as HBV treatment should be recommended for patients who do not have HIV and for whom PrEP is no longer indicated.
  • Discontinuation of TDF/FTC or TAF/FTC in patients with chronic HBV requires close monitoring for rebound HBV viremia.
  • Individuals with chronic HBV who are not candidates for PrEP should be evaluated for treatment that follows published guidelines [Terrault, et al. 2016]. For more information, see the NYSDOH AI guideline HBV-HIV Coinfection.

☑ If the patient is pregnant or attempting to conceive:
  • Information about the potential benefits and risks of taking TDF/FTC during pregnancy is an essential component of shared decision-making regarding risk reduction.
  • HIV acquisition risk is higher in pregnancy and is at its highest in the late pregnancy and early postpartum periods [Thomson, et al. 2018].
  • Risk of perinatal transmission is significantly higher during pregnancy and breastfeeding in the setting of acute seroconversion [Singh, et al. 2012; Drake, et al. 2014].
  • TDF/FTC as PrEP may be continued during pregnancy and breastfeeding if risk of HIV acquisition is ongoing.
  • Suppressive antiretroviral therapy (treatment as prevention) for the partner who has HIV is also important for risk reduction.
  • Prospectively report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry.

☑ If the patient is an adolescent:
  • TDF/FTC as PrEP is appropriate for adolescents who are at risk of acquiring HIV and weigh ≥35 kg (~77 lb).
  • A 2017 amendment to the New York Codes, Rules and Regulations (NYCRR), grants minors the capacity to consent to PrEP and PEP without parental/guardian involvement.

☑ If the patient is at risk of chronic kidney disease (e.g., age >40 years, hypertension, or diabetes), or has preexisting mild kidney disease with CrCl >60 mL/min:
  • The greater possibility of kidney disease among individuals who have preexisting risk factors is an essential component of the risk-benefit discussion and shared decision-making regarding initiation of TDF/FTC as PrEP.
  • More frequent renal monitoring may be required for patients at risk of renal disease or who are older than age 40 years who elect to use TDF/FTC as PrEP.
  • TAF/FTC, although not yet FDA-approved for use as PrEP, is an alternative to TDF/FTC for PrEP in MSM and transgender women with chronic kidney disease.

☑ If the patient is taking other medications:
  • A thorough medication history that includes over-the-counter medications, such as nonsteroidal anti-inflammatory drugs, may reveal concomitant nephrotoxic drugs and potential need for increased renal monitoring.

☑ If the patient has osteopenia, osteomalacia, or osteoporosis:
  • The risk of bone loss for individuals who have preexisting risk factors or documented osteopenia, osteomalacia, or osteoporosis is an important component of the risk-benefit discussion and shared decision-making regarding initiation of TDF/FTC as PrEP.
**Box 3: Important Clinical Considerations When Prescribing TDF/FTC as PrEP**

*TDF is approved by the FDA as treatment for HBV. FTC is also active against HBV but is not FDA-approved for HBV treatment. TDF in combination with FTC or lamivudine (3TC), which is FDA-approved for HBV treatment and is molecularly similar to FTC, is commonly used in patients with HIV-HBV coinfection as part of an antiretroviral regimen to treat both infections.

**REFERENCES**


