

PrEP Pre-Prescription Patient Education Checklist

Medical Care Criteria Committee, February 2020

PrEP PRE-PRESCRIPTION PATIENT EDUCATION CHECKLIST

From the New York State Department of Health AIDS Institute guideline *PrEP to Prevent HIV and Promote Sexual Health*

USE OF TDF/FTC AS PrEP

- Dosing and need for adherence.
- Time to protection is based on pharmacokinetic modeling studies and has not been clinically determined.
- For rectal exposure, protection against HIV acquisition is achieved after 7 days of TDF/FTC daily dosing and possibly earlier.
- For genital and blood exposure, protection against HIV acquisition is likely achieved after 7 days of TDF/FTC daily dosing, but optimal protection is achieved after 20 days of daily dosing.
- Taking 2 pills of TDF/FTC as PrEP on the day of initiation will decrease the time needed to achieve protective drug levels for all sites of exposure.

COMMON SIDE EFFECTS ASSOCIATED WITH TDF/FTC AND TAF/FTC

- Predominantly diarrhea, headache, abdominal pain, and dizziness.
- Side effects are usually mild, peak at 1 month, and resolve within 3 months.

LONG-TERM SAFETY OF TDF/FTC AND TAF/FTC AS PrEP

- Data suggest clinical safety of oral TDF/FTC and TAF/FTC in individuals without HIV. Although long-term safety has not been established in individuals without HIV, TDF/FTC has been used safely in thousands of individuals with HIV since 2004; 24-month follow-up data show clinical safety of oral TDF in men without HIV who have sex with men. TAF/FTC has been used safely in individuals with HIV since 2016.

POSSIBLE SYMPTOMS OF AND RESPONSE TO SEROCONVERSION/ACUTE HIV

- Contact healthcare provider if any of the following symptoms occur: fever, rash, joint pain, oral ulcers, fatigue, night sweats, sore throat, malaise, muscle pain, loss of appetite.
- Importance of prompt treatment plan in the event of HIV seroconversion.

CRITERIA FOR DISCONTINUING PrEP

- Positive HIV test result. ART will be offered, and follow-up diagnostic and HIV genotypic resistance testing should be performed.
- Development of renal disease; no data for adjusting TDF/FTC or TAF/FTC dosing in those with a decreased CrCl.
 - Daily PrEP with TDF/FTC should be discontinued if CrCl <50 mL/min.
 - TAF/FTC should be discontinued if CrCl <30 mL/min.
- Does not adhere to HIV testing requirements.

ADDED VALUE OF CONDOM USE

- PrEP greatly reduces but may not eliminate HIV transmission risk and does not protect against STIs other than HIV or against pregnancy.

USE OF PrEP DURING PREGNANCY

- **Benefits:** Decreased risk of HIV acquisition in the pregnant individual, which increases in pregnancy; decreased perinatal transmission. Acute HIV during pregnancy is a significant risk factor for perinatal transmission.
- **Potential toxicity:** Although available data suggest that TDF/FTC does not increase risk of birth defects, conflicting results have been observed in studies of BMD, ranging from no association to up to a 15% decrease in BMD in infants born to individuals receiving TDF, with limited data on long-term follow-up to determine the effect and longevity of this initial decrease in infant BMD. Data are insufficient to exclude the possibility of harm.
- **Benefit vs. risk:** For individuals who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individual decision based on whether ongoing or new risks for HIV acquisition are present during pregnancy.
- There are insufficient data on the safety of TAF/FTC in pregnancy, and TAF/FTC has not been studied for those having vaginal receptive sex.

Abbreviations: BMD, bone mineral density; CrCl, creatinine clearance; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine.