



✓ PrEP PRE-PRESCRIPTION PATIENT EDUCATION CHECKLIST

From the NYSDOH AIDS Institute guideline, PrEP to Prevent HIV Acquisition, available at www.hivguidelines.org

1. USE OF PrEP

- Dosing and need for daily adherence
- Number of sequential doses to achieve protective effect and differences in time to protection in men and women; available data suggest that it takes more time to accumulate protective drug concentrations in the female genital tract (20 days) than the rectum (7 days) ^[a]

2. COMMON SIDE EFFECTS

- Diarrhea, headache, abdominal pain, asthenia, and nausea
- Side effects are usually mild, peak at 1 month, and resolve within 3 months

3. LONG-TERM SAFETY OF PrEP ^[b]

- 24-month follow-up data suggest clinical safety of oral TDF in individuals without HIV infection

4. POSSIBLE SYMPTOMS OF SEROCONVERSION/ACUTE HIV INFECTION

- Contact their healthcare provider if they experience any of the following symptoms: fever, rash, joint pain, oral ulcers (mouth sores), fatigue, night sweats, sore throat, malaise, muscle pain, loss of appetite
- Importance of prompt treatment plan in the event of HIV seroconversion

5. CRITERIA FOR DISCONTINUING PrEP

- Positive HIV test result
 - PrEP should be discontinued, antiretroviral therapy (ART) should be offered, and follow-up diagnostic and HIV genotypic resistance testing should be performed
- Development of renal disease; there is no role for adjusting TDF dosing in those with Cr Cl <60. It should be discontinued if Cr Cl is ≤50
- Non-adherence to medication regimen or appointments
- Change in risk behaviors such that PrEP is no longer needed

6. ADDED VALUE OF CONDOM USE

- PrEP greatly reduces but may not eliminate HIV transmission risk
- PrEP does not protect against other sexually transmitted infections or pregnancy

7. USE OF PrEP DURING PREGNANCY

- Benefit: PrEP decreases the risk of acquiring acute HIV infection, which is a significant risk factor for mother-to-child transmission.
- Potential toxicity: Although available data suggest that TDF/FTC does not increase risk of birth defects, up to a 15% decrease in bone mineral density has been reported in infants born to women receiving TDF. Long-term follow-up data to determine the affect and longevity of this initial decrease in infant BMD are not yet available. Data are insufficient to exclude the possibility of harm. ^[c]
- Benefit vs Risk: For individuals who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether ongoing or new risks for HIV acquisition are present during pregnancy.

Notes:

- Based on modeling, 7 days of daily dosing is needed to achieve protective concentrations for receptive anal sex and 20 days of daily dosing is needed for receptive vaginal sex.*
- Although long-term safety has not been established in non-HIV-infected individuals, TDF/FTC has been used safely in thousands of individuals with HIV infection since 2004; 24-month follow-up data show clinical safety of oral TDF in men without HIV infection who have sex with men.*
- TDF/FTC is a preferred component of ART during pregnancy.*