Contact patient in 2 weeks to ensure:

- Patient has filled prescription
- Assure HIV test results are available and acted upon within 7 days of
  initiation
- TAF/FTC is an alternative regimen for cisgender MSM
- TDF/FTC is the preferred regimen.

If history of HBV, renal disease or recent symptoms of acute HIV, regardless of sites of reported exposure.

Key points—Before starting PrEP

Candidates for PrEP

- Clinicians should recommend PrEP with TDF/FTC (Truvada) for individuals, including adolescents (weighing ≥35 kg), who have adequate renal function and do not have but are at increased risk of acquiring HIV. (A1)
- For patients who are completing a course of nPEP and remain at risk for HIV, clinicians should recommend initiation of PrEP immediately after completion of nPEP. (A3)

Contraindications to TDF/FTC as PrEP

- TDF/FTC as PrEP is contraindicated for individuals (A1): With documented HIV (absolute contraindication) or with a confirmed CrCl <60 mL/min (relative contraindication; see text).

Pre-Prescription Medical Evaluation and Laboratory Testing

- Before prescribing PrEP, clinicians should perform a medical evaluation of the candidate that includes:
  - Laboratory testing (see PrEP Management Checklist: Pre-Prescription); assessment for symptoms or signs of acute HIV, including a febrile, flu-, or mono-like illness in the previous 6 weeks (A3); assessment to identify recent risk encounters (<72 hours) and the potential need for PEP prior to PrEP (A3); evaluation of concomitant medications to identify nephrotoxic drugs or drugs that have interactions with TDF/FTC as PrEP (A3); and inquiry about the individual’s reproductive plans. (A3)

Pre-Prescription Medical Evaluation and Laboratory Testing—continued

Pre-Prescription Medical Evaluation and Laboratory Testing—continued

Pre-Prescription Medical Evaluation and Laboratory Testing—continued

All recommendations—Before starting PrEP

Candidates for PrEP

- Clinicians should recommend PrEP with TDF/FTC (Truvada) for individuals, including adolescents (weighing ≥35 kg), who have adequate renal function and do not have but are at increased risk of acquiring HIV. (A1)
- For patients who are completing a course of nPEP and remain at risk for HIV, clinicians should recommend initiation of PrEP immediately after completion of nPEP. (A3)

Contraindications to TDF/FTC as PrEP

- TDF/FTC as PrEP is contraindicated for individuals (A1): With documented HIV (absolute contraindication) or with a confirmed CrCl <60 mL/min (relative contraindication; see text).

Pre-Prescription Medical Evaluation and Laboratory Testing

- Before prescribing PrEP, clinicians should perform a medical evaluation of the candidate that includes:
  - Laboratory testing (see PrEP Management Checklist: Pre-Prescription); assessment for symptoms or signs of acute HIV, including a febrile, flu-, or mono-like illness in the previous 6 weeks (A3); assessment to identify recent risk encounters (<72 hours) and the potential need for PEP prior to PrEP (A3); evaluation of concomitant medications to identify nephrotoxic drugs or drugs that have interactions with TDF/FTC as PrEP (A3); and inquiry about the individual’s reproductive plans. (A3)

Continued next panel >
✔ READINESS AND WILLINGNESS TO ADHERE TO PrEP
- Assess health literacy and assure that the purpose, benefits, and risks associated with PrEP are understood.
- Identify potential barriers to adherence.

✔ HIV STATUS OF PATIENT’S SEX PARTNER(S)
- Does the patient have sex partners who are known to have HIV?
  - If yes, ask about each partner:
    - Is the partner’s viral load status known?
    - Provide information about U=U.

✔ POTENTIAL DRUG-DRUG INTERACTIONS
- Take a thorough medication history that includes prescription drugs, over-the-counter drugs, and nonprescription therapies.
- Identify nephrotoxic medications and the potential need for increased renal monitoring.

✔ SUBSTANCE USE AND MENTAL HEALTH STATUS
- Refer to the Mental Health Screening quick reference guide.

✔ PSYCHOSOCIAL STATUS
- Perform a psychosocial assessment.
- Refer for appropriate social and psychological support services as indicated.

✔ REPRODUCTIVE PLANS
- Is the patient trying to conceive?
- Is the patient currently using contraception? If not, is the patient interested in using hormonal contraception or another effective method of contraception in addition to condoms?
- Is the patient or the patient’s partner currently pregnant?
- Is the patient currently breastfeeding?
- If yes to any of the above, consult the recommendations and information in the guideline section Pregnancy Screening and Management.

✔ PrEP PAYMENT ASSISTANCE
- Connect the individual to resources for assistance with payment, such as the NYSDOH PrEP Assistance Program.
- Other resources can be found through NYSDOH Payment Options for Pre-Exposure Prophylaxis (PrEP).

[a] Substance use, mental health disorders, and psychosocial challenges are not exclusionary criteria. Assessment allows the clinician to provide appropriate referrals and offer a tailored prevention plan. Substance use and mental health disorders may be barriers to adherence and cofactors for increased risk for HIV acquisition.

✔ 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 exposures, protection against HIV acquisition 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 at 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
- 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 PrEP
- Data suggest clinical safety of oral TDF/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.

✔ 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.
- Acute HIV during pregnancy is a significant risk factor for perinatal transmission. Acute HIV during pregnancy is a significant risk factor for perinatal transmission.

✔ USE OF TDF/FTC AS 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 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.

Use this code with your phone’s QR code reader to go directly to a mobile-friendly version of the guideline.

This ¼-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline PrEP to Prevent HIV Acquisition. The full guideline is available at www.hivguidelines.org.