INDIVIDUALS WITH WHOM CLINICIANS SHOULD DISCUSS PREP

- Individuals who engage in unprotected anal or vaginal intercourse with partners whose HIV status is unknown, have untreated HIV, or who do not have undetectable viral load while on treatment for HIV.
- Individuals who engage in unprotected anal or vaginal intercourse with partners who are HIV infected and are undetectable but wish to be on PrEP for additional protection.
- Women or men attempting to conceive with an HIV-infected partner.
- Women at ongoing risk of HIV acquisition during pregnancy.
- Individuals who engage in unprotected anal or vaginal intercourse with a partner with HIV infection, or both.

Clinicians should recommend PrEP for individuals, including adolescents, who do not have HIV infection and who self-identify as at risk without disclosing any specific risk behaviors or meet or acknowledge the risk criteria above. Such individuals include those who engage in insertive anal or vaginal sex, and injection drug use – 7 days of daily PrEP use for protection with receptive vaginal sex; 7 days of daily PrEP use for protection with receptive anal sex; or 20 days of daily PrEP use for protection with insertive anal sex. Indeterminate or negative pregnancy tests do not exclude risk for HIV. Although PrEP is not intended to substitute for other safer sex practices, safer sex and safe injection practices. (AII)

Note: PrEP also may be appropriate for individuals who do not currently meet or acknowledge the risk criteria above. Such individuals include those who self-identify as at risk without disclosing any specific risk behaviors and individuals who acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.

Turn over for Patient Evaluation, Patient Education, and Pre-Prescription Management checklists.
PrEP PRE-PRESCRIPTION PATIENT EVALUATION CHECKLIST

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

1. SYMPTOMS OF ACUTE HIV INFECTION
   ☐ Has the patient experienced a febrile, “flu”–, “mono”–like illness in the previous 6 weeks?
   ☐ Has the patient had a rash in the previous 6 weeks?

2. READINESS AND WILLINGNESS TO ADHERE TO PrEP
   ☐ Identify potential barriers to daily adherence
   ☐ Screen for health literacy

3. HIV STATUS OF PATIENT’S SEX PARTNER(S)
   ☐ Does the patient have sex partners who are known to be HIV–infected?
     If yes, ask about each partner:
     ☐ Is the partner taking antiretroviral therapy (ART)?
     ☐ Is the partner’s HIV viral load suppressed? If no, is a resistance profile available?

4. UNDERSTANDING OF PrEP
   ☐ Ask “Why do you want PrEP?”
   ☐ Ask “What is your understanding of what PrEP will do for you?”

5. POTENTIAL DRUG–DRUG INTERACTIONS
   ☐ Ask the patient to list all drugs he or she is taking, including prescription drugs, OTC drugs, and non-prescription therapies
   ☐ Identify nephrotoxic medications

6. SUBSTANCE USE AND MENTAL HEALTH STATUS*
   ☐ Refer to the Mental Health Screening quick reference guide
   ☐ Refer to the Substance Use Screening quick reference guide

7. PSYCHOSOCIAL STATUS*
   ☐ Screen for intimate partner violence; see NYS Office for the Prevention of Domestic Violence
   ☐ Assess relationships and social support status
   ☐ Assess housing status/instability

8. 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 other effective method of contraception in addition to condoms?
   ☐ Is the patient or the patient’s partner currently pregnant?
   ☐ Is the patient currently breastfeeding?

   ☐ 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 PrEP

   * 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.

PrEP MANAGEMENT CHECKLIST: PRE-PRESCRIPTION

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

1. PRE-PRESCRIPTION
   ☐ Discuss PrEP use; clarify any misconceptions
   ☐ Perform baseline laboratory testing:
     - HIV test (with HIV RNA testing if indicated)
     - Calculated creatinine clearance
     - Pregnancy test for women of childbearing potential
     - HBV serologies (HBsAg, anti–HBs, and anti–HBe–IgG or total)
     - HAV serology
     - STI screening (syphilis, gonorrhea, chlamydia)
     - HCV serology
     - Serum liver enzymes
     - Urinalysis

2. AFTER CONFIRMING NEGATIVE HIV TEST
   ☐ Prescribe 30–day supply of PrEP
   ☐ Contact patient in 2 weeks to assess for side effects
   ☐ Instruct patient to report side effects immediately

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 (TDF 300 mg/FTC 200 mg fixed dose tablet) 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

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 BMI are not yet available. Data are insufficient to exclude the possibility of harm [c].
   ☐ Benefit vs Risk: For women 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.
- c. TDF/FTC is a preferred component of ART during pregnancy.

REPORTING: Clinicians must report confirmed cases of HIV according to New York State Law.

Reporting of suspected seroconversion: Care providers who manage patients on PrEP are strongly encouraged to immediately report any cases of suspected PrEP or PEP breakthrough HIV infection as follows:

NYC: Report cases to the NYC DOHMH immediately by calling 212.442.3388.

Rest of State: Report cases to NYSDOH by calling 518.474.4284 or using DOH–4189 and contacting their local Partner Services Program to discuss the case.