ALL RECOMMENDATIONS – BEFORE STARTING PrEP

- Contraindications to PrEP:
  - Have unstable housing or limited social support (AIII)
  - Mental health disorders (AIII)
  - Reported substance use (AI)
  - Report inconsistent use of or adherence to other risk reduction practices, including safer sex and safe injection practices (AIII)
  - Have a history of mental illness and drug use (AIII)
  - Engage, or whose partners may engage, in any of the following behaviors (AI):
    - Have, or whose partners may have, multiple or anonymous sex partners
    - Engage, or whose partners may engage, in sexual activity at sex parties or other high-risk venues
    - Are involved, or whose partners may be involved, in transactional sex, such as for money, drugs, or housing, including commercial sex workers and their clients
    - Have been diagnosed with at least one sexually transmitted infection in the previous 12 months
    - Report recreational use of mood-altering substances during sex, such as alcohol, methamphetamine, cocaine, and ecstasy
    - Report injecting substances, or have partners who inject substances, including illicit drugs and hormones
  - Are receiving nPEP and demonstrate continued high-risk behavior or have used multiple courses of nPEP

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?
- Is the partner taking antiretroviral therapy (ART)?
- Is the partner’s viral load suppressed?

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/stability

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 in 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–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 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:
- a. 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.
- b. 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.