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 parters 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. Ongoing risk for serodifferent couples during pregnancy includes inconsistent condom use, incomplete viral suppression in the partner with HIV infection, or both.
- Those who:
  - 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 sex 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. →

ALL RECOMMENDATIONS – BEFORE STARTING PrEP *Continued*

- Obtain a thorough sexual history and drug use history, identify risk-taking behaviors, encourage safer sex practices, and, if applicable, safer drug injection techniques. (AII)
- Perform a psychosocial assessment and refer for appropriate social and psychological support services, as indicated, to minimize HIV risk and support maintenance in care. (BIII)
- Perform substance use and mental health screenings. (AIII)

Pre-Prescription Laboratory Tests: Before prescribing PrEP, clinicians should perform a medical evaluation of the candidate that includes the following:

- Laboratory testing—see *Recommended Laboratory Tests to be obtained before Prescribing PrEP (inside, bottom left).*
- Assessment for symptoms or signs of acute HIV infection, including a febrile, "flu"-, or "mono"-like illness in the previous 6 weeks. (AII)
- Evaluation of concomitant medications to identify nephrotoxic drugs or drugs that have interactions with the PrEP regimen. (AIII)
- Inquiry about the individual's reproductive plans. (AIII)
- Clinicians should prescribe PrEP only after receiving a negative 4th generation (recommended) or 3rd generation (alternative) HIV test within 1 week of planned PrEP initiation. (AIII)
- If the HIV test result is not available during the patient visit, the clinician should contact the patient to discuss the test result once it is available; if the result is negative, then the clinician should contact the patient's pharmacy to prescribe PrEP. (AIII)

Prescribing PrEP: Clinicians should initially prescribe only a 30-day supply of PrEP (the adult dose is TDF 300 mg/FTC 200 mg fixed dose tablet); once adherence and tolerance is assessed, a 90-day supply can be prescribed. (AIII)

- Clinicians should educate patients about the time required to achieve protective concentrations of TDF/FTC for PrEP (AII):
  - 7 days of daily PrEP use for protection with receptive anal sex
  - 20 days of daily PrEP use for protection with receptive vaginal sex, insertive anal or vaginal sex, and injection drug use

ALL RECOMMENDATIONS – BEFORE STARTING PrEP

- **Candidates for PrEP:** Clinicians should recommend PrEP for individuals, including adolescents, who do not have HIV infection and are at high risk of acquiring HIV and have adequate renal function. (AI)
- For patients who are completing a course of non-occupational PEP (nPEP), clinicians should recommend initiation of PrEP immediately after completion of nPEP. (AIII)
- **Contraindications to PrEP:** Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) as PrEP is contraindicated for individuals with documented HIV infection (AI) and for those with a creatinine clearance <60 mL/min (AI).

Pre-Prescription Assessment and Evaluation:

Clinicians should ***not*** withhold PrEP from candidates who:

- Use other risk reduction practices inconsistently (AIII)
- Report substance use (AI)
- Have mental health disorders (AIII)
- Report intimate partner violence (AIII)
- Have unstable housing or limited social support (AIII)

Clinicians should:

- Assess the individual's health literacy and ensure that he or she understands the purpose, benefits, and risks associated with PrEP. (AIII)
- Individualize the decision to initiate PrEP by weighing the benefit of reducing a patient's personal risk of acquiring HIV infection against the potential adverse effects of the medication. (AIII)
- Make clear that PrEP efficacy is highly dependent on daily adherence, assess for readiness and willingness to adhere to PrEP and recommended follow-up care, and assess for barriers to adherence. (AIII)
- Ask whether the individual has a sex partner (or partners) with known HIV infection; if yes, ask if partner's viral load status is known. (BIII)
- Counsel serodifferent couples who are considering using PrEP during attempts to conceive about the utility, safety, and possible risks of the medications and about other approaches to safer conception. (AIII)

HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

VISIT **HIVGUIDELINES.ORG** TO LEARN MORE OR VIEW COMPLETE GUIDE

PrEP GUIDELINE: PRE-PRESCRIPTION

NYSDOH AIDS INSTITUTE PrEP CLINICAL GUIDELINE OCTOBER 2017

→ KEY POINTS

- In New York State, use of TDF/FTC as PrEP is a central component of the standard of care for prevention of HIV acquisition in those at high risk.
- A comprehensive HIV prevention plan includes PrEP, along with safer sex and safe injection practices.
- PrEP should not be withheld from people of any age group who are at risk of HIV acquisition.
- Education regarding the importance of and strategies to support adherence may improve adherence to the daily PrEP regimen and recommended monitoring.
- For those who are unable to adhere to a daily medication regimen or recommended monitoring, alternative methods of HIV prevention should be explored and reinforced.
- If PrEP is to be initiated, the clinician can connect the patient to resources for assistance with payment, such as the NYSDOH PrEP Assistance Program (PrEP-AP) and NYSDOH Payment Options for PrEP.

← 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.

✔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?

9. 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 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-HBc-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

❍ 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 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.