ALL RECOMMENDATIONS–AFTER PrEP HAS BEEN STARTED

Symptomatic Patients: For patients who present with any symptoms of acute retroviral illness and for whom acute HIV infection is suspected, clinicians should perform a plasma HIV RNA assay in conjunction with an HIV screening test. (All)
- The patient should continue PrEP until results are available, preferably within 1 week. (BIII)
- For patients who receive a nonreactive screening result with HIV RNA ≥5,000 copies/mL, a clinician: 1) can make a presumptive diagnosis of HIV infection (All); 2) should recommend ART (All); and 3) should perform HIV genotypic resistance testing; adjustments to the initial ART regimen can be made according to genotypic resistance results or side effects. (All)
- For patients who receive a nonreactive HIV screening result but have detectable HIV RNA with <5,000 copies/mL, repeat HIV RNA to exclude a false-positive result after discontinuation of PrEP; ART may be offered as described above for patients with a nonreactive screening result with HIV RNA ≥5,000 copies/mL while awaiting results from repeat HIV RNA testing. (All)

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.

Turn over for the PrEP Management Checklist and Recommended PrEP Monitoring and Ongoing Lab Testing.
**PrEP MANAGEMENT CHECKLIST: FOLLOW-UP & MONITORING**
From the NYSDOH AIDS Institute guideline, PrEP to Prevent HIV Acquisition, available at www.hivguidelines.org

- **ALWAYS ENSURE ADHERENCE**
  - Assess adherence and commitment at EVERY visit
  - Schedule visits every 30 days for patients who report poor adherence or intermittent use of PrEP

- **30-DAY FOLLOW-UP VISIT**
  - Assess for side effects
  - Obtain serum creatinine and calculated creatinine clearance* for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
  - Discuss risk reduction, provide condoms and, if applicable, provide syringes
  - If adherence has been good, prescribe a 90-day refill
  - Inform about need for 3-month visit for HIV test and follow-up

- **3-MONTH VISIT**
  - Perform HIV and syphilis tests; screen for gonorrhea and chlamydia
  - Ask about symptoms suggestive of STIs and test those at high risk
  - Screen for symptoms of acute HIV infection and test if indicated
  - Perform pregnancy test for women of childbearing potential who are not using effective contraception or present with an STI
  - Obtain serum creatinine and calculated creatinine clearance*
  - Discuss risk reduction, provide condoms and, if applicable, provide syringes
  - Assess adherence; if adherence has been good, provide a 90-day prescription

- **6-MONTH VISIT**
  - Perform HIV and syphilis tests; screen for gonorrhea and chlamydia
  - Ask about symptoms suggestive of STIs and test those at high risk
  - Screen for symptoms of acute HIV infection and test if indicated
  - Perform pregnancy test for women of childbearing potential who are not using effective contraception or present with an STI
  - Perform STI screening tests
  - Discuss risk reduction, provide condoms and, if applicable, provide syringes
  - Assess adherence; if adherence has been good, provide a 90-day prescription

- **9-MONTH VISIT**
  - Perform HIV and syphilis tests; screen for gonorrhea and chlamydia
  - Ask about symptoms suggestive of STIs and test those at high risk
  - Screen for symptoms of acute HIV infection and test if indicated
  - Perform pregnancy test for women of childbearing potential who are not using effective contraception or present with an STI
  - Obtain serum creatinine and calculated creatinine clearance*
  - Discuss risk reduction, provide condoms and, if applicable, provide syringes
  - Assess adherence; if adherence has been good, provide a 90-day prescription

- **12-MONTH VISIT**
  - Perform HIV and syphilis tests; screen for gonorrhea and chlamydia
  - Urinalysis
  - Perform pregnancy test for women of childbearing potential who are not using effective contraception or present with an STI
  - Perform STI screening tests
  - Discuss risk reduction, provide condoms and, if applicable, provide syringes
  - Assess adherence; if adherence has been good, provide a 90-day prescription
  - Obtain HCV serology and serum liver enzymes for men who have sex with men, people who inject drugs, and those with multiple sexual partners

* There is no role for adjusting TDF dosing in those with Cr Cl <60—discontinue if Cr Cl ≤50.

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**RECOMMENDED MONITORING OR LABORATORY TESTING AND FREQUENCY FOR INDIVIDUALS ON PrEP**
From the NYSDOH AIDS Institute guideline, PrEP to Prevent HIV Acquisition, available at www.hivguidelines.org

- **HIV testing:**
  4th generation (recommended) or 3rd generation assay (alternative) HIV screening test every 3 months (AII).

- **HIV serology screening test + HIV RNA test:**
  - When a patient has symptoms of acute HIV infection or a negative antibody test but reports condomless anal or vaginal sex in the previous 4 weeks (AII).

- **Serum creatinine and calculated creatinine clearance:**
  - Perform 3 months after initiation and every 6 months thereafter while patient is taking TDF/FTC as PrEP (AIII).

- **HCV serology:**
  - Annually for those at risk (AII).

- **STI screening:**
  - As follows (AII). Note: self-collected rectal and vaginal swabs are reasonable options for patients who may prefer them over clinician-obtained swabs:
    - **Ask about symptoms:** Every visit
    - **Screen for syphilis:** Every 3 months for high risk men who have sex with men; at least annually for individuals at lower risk; on demand. (Clinicians should be aware of the syphilis screening algorithm used by their laboratory.)
    - **Screen for gonorrhea and chlamydia:** Every 3 months in high risk individuals; annually for individuals at lower risk; on demand. Extragenital screening (rectal and pharyngeal) should be performed for patients at high risk, including men who have sex with men and transgender women (MtF)
    - **Test and treat all symptomatic patients for STIs**

- **Pregnancy testing in women of childbearing potential:**
  - Every 3 months if effective contraception is not in use; annually if effective contraception is in use; whenever a new STI is diagnosed (AII)

- **Urinalysis:**
  - Annually (BII).

- **HCV RNA; HBV serology, if status is unknown; HBV DNA, if not immune; HAV serology, if unknown:**
  - If a new elevation in serum liver enzymes is present (good practice).

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**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.