ALL RECOMMENDATIONS–AFTER PrEP HAS BEEN STARTED *P.1*

PrEP Follow-Up: Upon initiation of PrEP, clinicians should instruct patients to notify their care provider immediately if they experience side effects. (BIII)

Within 2 weeks of PrEP initiation, clinicians should follow up with the patient to: 1) ensure the prescription was filled; 2) troubleshoot problems with payment and connect the patient to resources for payment if needed; and 3) inquire about side effects and proper use of PrEP. (BIII)

At each visit, clinicians should: 1) assess adherence and discuss strategies for maintaining adherence; 2) discuss risk reduction in the context of the individual's sexual health and/or injection drug use needs; 3 offer condoms, and, if appropriate, syringe access; and 4) manage side effects. (BIII)

Adherence and Retention in Care: Clinicians should provide adherence counseling during every patient contact. (AIII)

Risk Reduction: As an approach to decreasing acquisition of HIV and other STIs, clinicians should offer male and female condoms to all patients, including those using PrEP, at each visit. (AIII)

For patients who inject drugs, and others who misuse mood-altering drugs, clinicians should: 1) make referrals for substance use treatment and mental health support as appropriate (AIII) and 2) prescribe clean syringes and needles or refer to needle-exchange programs as indicated (AII).

For patients in serodifferent relationships, clinicians should discuss at each visit the benefits and risks of treatment as prevention (TasP) alone versus TasP + PrEP strategies for preventing transmission of HIV. (BIII)

PrEP Monitoring and Ongoing Laboratory Testing: Clinicians should perform routine monitoring of patients using PrEP according to the recommendations in *Recommended PrEP Monitoring and Laboratory Testing.*

ALL RECOMMENDATIONS–AFTER PrEP HAS BEEN STARTED *P.2*

Discontinuation of PrEP: Clinicians should discontinue PrEP in any patient who: 1) has a confirmed positive HIV test (AI); 2) develops a GFR ≤50 mL/min on PrEP with TDF/FTC (AII); or 3) does not adhere to HIV testing requirements (AIII).

Clinicians should closely monitor patients who have chronic HBV infection for potential rebound when PrEP with TDF/FTC is discontinued and develop an alternative treatment plan. (AII)

HIV Acquisition While Using PrEP: Clinicians should inform patients with suspected acute HIV infection about the increased risk of transmitting HIV during acute HIV infection (AII)

Asymptomatic Patients: For asymptomatic patients who receive a reactive HIV screening result while using PrEP, clinicians should:

- Discontinue PrEP immediately; if supplemental laboratory testing does not confirm HIV infection, PrEP may be resumed. (AI)
- PrEP should also be discontinued for those no longer at risk of HIV acquisition because they have eliminated the sex or drug use behaviors that put them at risk of acquiring HIV.
- In consultation with an experienced HIV care provider, recommend initiation of ART with at least 3 fully active ARVs. (AI)
- Perform supplemental diagnostic testing according to the CDC's HIV testing algorithm. (AI)
- Ask about medication interruption of any duration and discuss any access or adherence barriers. (AIII)
- If supplemental laboratory testing confirms HIV infection, clinicians should:
  - Perform HIV RNA testing, if not already obtained as part of the diagnostic algorithm for suspected acute HIV infection, to measure viral load. (AII)
  - Perform HIV genotypic resistance testing. Adjustments to the initial ART regimen can be made once genotypic resistance results are available or when considering side effects. (AII)

ALL RECOMMENDATIONS–AFTER PrEP HAS BEEN STARTED *P.3*

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. (AII)

- 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 (AII); 2) should recommend ART (AII); 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. (AII)
- 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. (AII)

Turn over for the PrEP Management Checklist and Recommended PrEP Monitoring and Ongoing Lab Testing. ☐

HIV CLINICAL RESOURCE ▪ ¼-FOLDED GUIDE

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

PrEP GUIDELINE: FOLLOW-UP

NYSDOH AIDS INSTITUTE PrEP CLINICAL GUIDELINE OCTOBER 2017

- 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 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 individuals 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 individuals 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 individuals 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 individuals 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.*

☐ 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 (AIII).
- ☐ **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 (AIII).
- ☐ **STI screening:**
  As follows (AIII). 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 individuals 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 (AIII)
- ☐ **Urinalysis:**
  Annually (BIII).
- ☐ **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).

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.