HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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PrEP TO PREVENT HIV & PROMOTE SEXUAL HEALTH

Candidates, Clinical Considerations, and Laboratory Testing

NYSDOH AIDS INSTITUTE PrEP CLINICAL GUIDELINE FEBRUARY 2020

INDIVIDUALS WHO SHOULD BE OFFERED PrEP *P. 1*

Candidates who should be offered PrEP include individuals who:

- Engage in condomless sex with partners whose HIV status is unknown, or who have untreated HIV, or who have unsuppressed virus while on treatment for HIV.
- Are attempting to conceive with a partner who has HIV.
- Are at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus.
- Have, or are involved with partners who may have, multiple or anonymous sex partners.
- Engage in sexual activity at parties and other high-risk venues, or have sex partners who do so.
- Are involved, or have partners who may be involved, in transactional sex (i.e., sex for money, drugs, food, or housing), including commercial sex workers and their clients.
- Have been diagnosed with at least 1 bacterial STI in the previous 12 months.
- Report recreational use of mood-altering substances during sex, including but not limited to alcohol, methamphetamine, cocaine, ecstasy, and gamma hydroxybutyrate.
- Report injecting substances or having sex partners who inject substances, including illicit drugs, hormones, or silicone.
- Are receiving nPEP and anticipate ongoing risk or have used multiple courses of nPEP.
- Request the protection of PrEP even if their sex partners have an undetectable HIV VL (see discussion of U=U in full guideline).
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.

INDIVIDUALS WHO SHOULD BE OFFERED PrEP, *continued* *P. 2*

***Do not withhold* PrEP from candidates who:**

- Are pregnant or planning a pregnancy.
- Use other risk-reduction practices inconsistently, including condoms.
- Report substance use.
- Have mental health disorders, including serious persistent mental illness.
- Report intimate partner violence.
- Have unstable housing or limited social support.
- Report a recent STI.
- Request PrEP even in they have a partner living with HIV with an undetectable VL.

IMPORTANT CLINICAL CONSIDERATIONS WITH TDF/FTC OR TAF/FTC AS PrEP

If the patient has chronic active HBV:

- TDF, TAF, and FTC are active against HBV. For more information, see *AASLD guidelines for treatment of chronic hepatitis B.*
- TDF and TAF are approved by the FDA for the treatment of HBV. When taken daily, TDF/FTC or TAF/FTC may be used as PrEP and concomitant HBV treatment [a].
- Continuation of TDF, TDF/FTC, TAF, or TAF/FTC as HBV treatment should be recommended for patients who do not have HIV and for whom PrEP is no longer indicated.
- Discontinuation of TDF/FTC or TAF/FTC in patients with chronic HBV requires close monitoring for rebound HBV viremia.
- Individuals with chronic HBV who are not candidates for PrEP should be evaluated for treatment that follows published guidelines. For more information, see the NYSDOH AI guideline *HBV-HIV Coinfection.*

If the patient is pregnant or attempting to conceive:

- TAF/FTC is not approved for use as PrEP in this population.
- Information about the potential benefits and risks of taking TDF/FTC during pregnancy is an essential component of shared decision-making regarding risk reduction.

IMPORTANT CLINICAL CONSIDERATIONS WITH TDF/FTC OR TAF/FTC AS PrEP, *continued* *P. 3*

If the patient is pregnant or attempting to conceive, *continued*:

- HIV acquisition risk is higher in pregnancy and is at its highest in the late pregnancy and early postpartum periods.
- Risk of perinatal transmission is significantly higher during pregnancy and breastfeeding in the setting of acute seroconversion.
- TDF/FTC as PrEP may be continued during pregnancy and breastfeeding if risk of HIV acquisition is ongoing.
- Suppressive ART (treatment as prevention) for the partner who has HIV is also important for risk reduction.
- Prospectively report information regarding use of PrEP during pregnancy to the *Antiretroviral Pregnancy Registry.*

If the patient is an adolescent:

- TDF/FTC (for all populations) and TAF/FTC (for cisgender MSM and transgender women) as PrEP are appropriate for adolescents who are at risk of acquiring HIV and weigh ≥35 kg (~77 lb).
- A 2017 amendment to the NYCRR grants minors the capacity to consent to PrEP and PEP without parental/guardian involvement.

If the patient is at risk of chronic kidney disease (e.g., age >40 years, hypertension, or diabetes), or has preexisting mild kidney disease with CrCl <60 mL/min:

- The greater possibility of kidney disease among individuals who have risk factors is an essential component of the risk-benefit discussion and shared decision-making regarding initiation of TDF/FTC or TAF/FTC as PrEP.
- More frequent renal monitoring may be required for patients at risk of renal disease or who are older than age 40 years who elect to use TDF/FTC or TAF/FTC as PrEP.
- TDF/FTC should not be initiated with a CrCl of <60 mL/min. TAF/FTC is an option for PrEP in MSM and transgender women with renal disease and a CrCl >30 mL/min.

If the patient is taking other medications:

- A thorough medication history that includes over-the-counter medications, such as NSAIDs, may reveal concomitant nephrotoxic drugs and potential need for increased renal monitoring.

IMPORTANT CLINICAL CONSIDERATIONS WITH TDF/FTC OR TAF/FTC AS PrEP, *continued* *P. 4*

If the patient has osteopenia, osteomalacia, or osteoporosis:

- The risk of bone loss for individuals who have preexisting risk factors or documented osteopenia, osteomalacia, or osteoporosis is an important component of the risk-benefit discussion and shared decision-making regarding initiation of TDF/FTC as PrEP. TAF/FTC is preferred for cisgender MSM and transgender women with osteoporosis.

a. TDF and TAF are approved by the FDA as treatment for HBV. FTC is also active against HBV but is not FDA-approved for HBV treatment. TDF or TAF in combination with FTC or 3TC, which is FDA-approved for HBV treatment and is molecularly similar to FTC, are commonly used in patients with HIV-HBV coinfection as part of an antiretroviral regimen to treat both infections.

TDF/FTC VERSUS TAF/FTC AS PrEP

	TDF/FTC	TAF/FTC
Effectiveness	All populations.	Cisgender MSM and transgender women [a].
Renal safety	• Potential effect on renal tubular function. Meta-analysis shows good safety. • Discontinue if confirmed CrCl <50 mL/min.	• Improved renal biomarkers compared to TDF. • Can be used with stage 3 CKD (CrCl 30-59 mL/min).
Bone safety	Potential decrease in bone mineral density. Meta-analysis shows good safety.	Favorable bone biomarkers compared with TDF.
Weight	Weight neutral.	Mild weight gain observed in studies.
LDL cholesterol	Small decreases.	Small increases.
Dosing	Daily dosing is preferred. On-demand dosing is an option in cisgender MSM.	Daily dosing only.
Cost	Will go off patent in 2020.	Currently similar to TDF/FTC.

a. Transgender women made up only 1% of the DISCOVER study population.

PRE-RX: RECOMMENDED LAB TESTS TO BE OBTAINED BEFORE PRESCRIBING TDF/FTC OR TAF/FTC AS PREP

Note: PrEP may be initiated while results are pending.

Test (rating)	**Comments**
Baseline HIV test (A*)	• Obtain a 4th-generation (recommended) or 3rd-generation (alternative) HIV screening test.
HIV RNA testing (A3)	• Perform HIV RNA testing in patients who: Have had symptoms of acute HIV in the past 6 weeks; report condomless anal or vaginal sex during the previous 4 weeks; or have shared injection drug needles in the past 4 weeks.
Metabolic panel (A*)	• Obtain serum creatinine and calculated CrCl. • TDF/FTC as PrEP should not be initiated in patients with a confirmed calculated CrCl <60 mL/min. • TAF/FTC should not be initiated in patients with a confirmed calculated CrCl <30 mL/min.
Pregnancy test for all individuals of childbearing capacity (A3)	• Discuss the importance of preventing HIV during pregnancy with anyone contemplating pregnancy or who becomes pregnant while taking PrEP. Discuss overall risks and benefits and available data, which suggest that TDF/FTC does not increase risk of birth defects.
HBV serologies: HBsAg, anti-HBs, and anti-HBc [IgG or total] (A2†)	• Vaccinate nonimmune patients. (A2) • Chronic HBV: Treat and monitor HBV as per treatment guidelines, or refer to an HBV specialist.
Gonorrhea and chlamydia screening (A2†)	• Perform NAATs for gonococcal and chlamydial infections for all patients at all sites of reported exposure. • For all MSM and transgender women, routinely perform 3-site testing (genital, rectal, and pharyngeal) regardless of sites of reported exposure. • Genital testing: – To detect urethral infection, urine specimens are preferred over urethral specimens. – For vaginal/cervical testing, vaginal swabs are preferred over urine-based testing. – For transgender women with a neovagina, there are insufficient data to make a recommendation regarding urine-based testing vs. vaginal swab. • Self-collected swabs from the pharynx, vagina, and rectum are reasonable options for patients who may prefer them over clinician-obtained swabs.
Syphilis screening (A2†)	• Screen for syphilis according to the lab's testing algorithm.
HCV serology (A3)	• Inform patients with HCV about the risk of transmission and offer or refer for treatment.
HAV serology (good practice)	• Obtain for individuals at high risk for HAV, including MSM and those who: – Have chronic liver disease or conditions that can lead to chronic liver disease (e.g., chronic HBV, chronic HCV, alcohol use, or genetic liver diseases). – Are travelers to or from countries with high or intermediate endemicity of HAV infection. – Use illicit drugs, particularly injection drugs. – Are unstably housed/homeless. – Live in a community identified by the local health department as experiencing an outbreak of HAV infection. – Have clotting-factor disorders. – Want to reduce their risk for HAV infection. – Are at occupational risk and are not otherwise required to receive HAV vaccination. – Are at risk of HAV-related morbidity or mortality. • Vaccinate nonimmune patients.
Serum liver enzymes (good practice)	• Increased serum liver enzymes may indicate acute or chronic viral hepatitis infection and require further evaluation.
Urinalysis (good practice)	• As part of standard primary care, urinalysis is used to identify preexisting renal disease, proteinuria, and glycosuria. • Only calculated CrCl is used to guide decisions regarding use of TDF/FTC and TAF/FTC as PrEP based on renal function.

ONGOING: RECOMMENDED MONITORING AND ONGOING LAB TESTING FOR PATIENTS TAKING TDF/FTC OR TAF/FTC AS PREP

Note: Recommended testing does not have to be linked to an office or clinic visit.

Monitoring or Laboratory Test (rating)	**Frequency** (rating)
HIV testing: 4th-generation (recommended) or 3rd-generation assay (alternative) HIV screening test	• 1 month after initiation for individuals with risk exposure within 1 month prior to PrEP initiation. (A2†) • Every 3 months while a patient is using PrEP. (A3)
HIV serology screening test plus HIV RNA test	• When a patient has: – Symptoms of acute HIV. (A2) – When there has been an interruption in PrEP in the past month and a potential exposure has occurred. (A3)
Serum creatinine and calculated CrCl	• 3 months after initiation (B3) and every 6 months thereafter while taking TDF/FTC or TAF/FTC as PrEP. (A3) • Consider more frequent screening in those at higher risk (e.g., age >40 years, other comorbidities). (A3)
STI screening (A2†): • Ask about STI symptoms • Test for syphilis • Test for gonococcal and chlamydial infections • Test and empirically treat all symptomatic patients for STIs	• Ask about symptoms at every visit. – For patients who present with symptoms, perform STI testing and treat as appropriate. • Test for syphilis, gonorrhea, and chlamydia every 3 months regardless of symptoms and on patient request. Frequency can be adjusted based on risk assessment and occur less often in patients at lower risk of exposure. • Perform NAATs for gonococcal and chlamydial infections for all patients at all sites of reported exposure. • For all MSM and transgender women, routinely perform 3-site testing (genital, rectal, and pharyngeal) regardless of sites of reported exposure unless declined. • Genital testing: – To detect urethral infection, urine specimens are preferred over urethral specimens. – For vaginal/cervical testing, vaginal swabs are preferred over urine-based testing. – For transgender women with a neovagina, data are insufficient to make a recommendation regarding urine-based testing vs. vaginal swab. • Self-collected swabs from pharynx, vagina, and rectum are reasonable options for patients who may prefer them over clinician-obtained swabs.
HCV serology (A3)	• At least annually for those at risk.
Pregnancy screening in individuals of childbearing capacity (A3)	• Assess for possibility of pregnancy at every visit. • Offer birth control when appropriate. • Test for pregnancy when appropriate and on patient request.
Urinalysis (B3)	• Annually.

RESOURCES: PREP PAYMENT ASSISTANCE

- For PrEP payment assistance, see NYSDOH *Payment Options for Adults and Adolescents for PrEP and PrEP Patient Assistance Program (PrEP-AP)*.
- In July 2019, the NYS Department of Financial Services issued a *Circular Letter* instructing health insurers to provide coverage for PrEP medications without cost-sharing, including co-pays and deductibles.

← 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 and Promote Sexual Health*. The full guideline is available at www.hivguidelines.org.