HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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PrEP TO PREVENT HIV & PROMOTE SEXUAL HEALTH

All Recommendations and Selected Key Points

NYSDOH AIDS INSTITUTE PrEP CLINICAL GUIDELINE FEBRUARY 2020

ALL RECOMMENDATIONS *P. 1*

Candidates for PrEP

- Clinicians should recommend PrEP for individuals, including adolescents [a], who do not have but are at increased risk of acquiring HIV. (A1)
- For patients who are completing a course of non-occupational PEP and remain at risk for HIV, clinicians should recommend initiation of PrEP immediately after completion of nPEP. (A3)

Contraindications to TDF/FTC and TAF/FTC as PrEP

- TDF/FTC and TAF/FTC as PrEP are contraindicated for individuals (A1):
  - With documented HIV (in such cases, a full therapeutic regimen is required; see NYSDOH AI guideline *Selecting an Initial ART Regimen*).
  - TDF/FTC: With a confirmed CrCl <60 mL/min.
  - TAF/FTC: With a confirmed CrCl <30 mL/min.

Pre-Prescription Medical Evaluation and Laboratory Testing

- Before prescribing PrEP, clinicians should perform a medical evaluation of the candidate that includes:
  - Assessment for symptoms or signs of acute HIV, including a febrile, flu-, or mono-like illness in the previous 6 weeks. (A3)
  - Assessment to identify recent risk encounters (<72 hours) and the potential need for PEP prior to PrEP. (A3)
  - Inquiry about the individual's reproductive plans. (A3)
  - Evaluation of concomitant medications to identify nephrotoxic drugs or drugs that have interactions with TDF/FTC or TAF/FTC as PrEP. (A3)
  - Laboratory testing listed in *Table 2: Recommended Laboratory Tests to Be Obtained Before Prescribing PrEP* (see full guideline).

Pre-Prescription Medical Evaluation and Laboratory Testing, *continued*

- Clinicians should prescribe PrEP only after obtaining a specimen for testing using a 4th-generation Ag/Ab (recommended) or 3rd-generation IgM/IgG antibody (alternative) HIV test and, when appropriate, an HIV viral load test [b] within 1 week before planned PrEP initiation. (A3)
  - PrEP may be initiated while results of laboratory-based HIV diagnostic tests are pending unless the individual had a high-risk exposure within the previous 72 hours that requires PEP, has symptoms or signs of acute HIV, or has a history of renal disease or HBV. (A2)
  - Clinicians should assure HIV test results are available and acted upon within 7 days of initiation. (A3)

Prescribing PrEP

- TDF/FTC is the preferred regimen for PrEP. Clinicians should prescribe TDF 300 mg/FTC 200 mg once daily with or without food as PrEP. (A1)
  - TAF 25 mg/FTC 200 mg once daily with or without food is an option for prevention of HIV through sexual exposure in cisgender MSM and transgender women. TAF 25 mg/FTC 200 mg is not a recommended option for sexual exposure through receptive vaginal sex.
  - TAF/FTC as PrEP is preferred in cisgender MSM and transgender women who have preexisting renal disease or osteoporosis.
- If daily dosing is a barrier to adherence or if episodic dosing is preferred, clinicians should evaluate the appropriateness of on-demand dosing of TDF/FTC as PrEP. (A3)

Monitoring

- Clinicians should perform routine monitoring of patients using PrEP according to the recommendations in *Table 3: Recommended PrEP Monitoring and Laboratory Testing* (see full guideline).

HIV Testing

- Clinicians should:
  - Obtain a 4th-generation (recommended) or 3rd-generation (alternative) laboratory-based HIV screening test before initiation of PrEP. (A*)
  - Repeat HIV testing 1 month after initiation for those reporting a risk exposure in the 30 days prior to PrEP initiation. (A2†)
  - Perform HIV testing every 3 months while a patient is using PrEP. (A3)

HIV Testing, *continued*

- If a patient presents with symptoms or signs of a flu-like illness consistent with possible acute retroviral syndrome, clinicians should perform HIV testing immediately according to guidelines for the evaluation of acute HIV, including an HIV viral load test and a laboratory-based 4th-generation HIV test. (A2)

Renal Function Testing

- At the following intervals, clinicians should perform renal function testing, including testing serum creatinine level and calculated CrCl :
  - Before initiating PrEP with TDF/FTC or TAF/FTC. (A*)
  - At 3 months after initiation. (B3)
  - At least every 6 months for the duration of use of TDF/FTC or TAF/FTC as PrEP; more frequent screening may be required in patients at higher risk for renal disease. (A3)
- Clinicians should discontinue daily TDF/FTC as PrEP if a patient develops a confirmed calculated CrCl ≤50 mL/min and consider other alternative dosing and options; see discussion in full guideline text for strategies and options for patients with reduced renal function. (A3)
- Clinicians should perform urinalysis at baseline and annually, assessing for urine glucose and protein. (B3)

STI Testing

- At every visit, a care team member should assess patients for signs and symptoms of STIs, including syphilis and gonococcal and chlamydial infections, as part of a sexual history and treat these infections empirically based on symptoms while results are pending. (A2†)
- Clinicians should perform ongoing testing for syphilis and gonococcal and chlamydial infections every 3 months at all sites of exposure, regardless of symptoms, as specified in *Table 3: Recommended PrEP Monitoring and Ongoing Laboratory Testing* (see full guideline). (A2†)

Hepatitis C Virus Testing

- Clinicians should obtain at least annual HCV testing for at-risk patients using PrEP. (A3)

Pregnancy Screening and Management

- Clinicians should discuss possibility of pregnancy in individuals of childbearing potential at every visit. (A3)

Discontinuing PrEP

- Clinicians should discontinue PrEP in any patient who:
  - Has a confirmed positive HIV test. (A1) In this case, the ARV regimen should be converted to a fully active ART regimen. (A1) See the NYSDOH guideline *When to Initiate ART, With Protocol for Rapid Initiation*.
  - Develops a confirmed calculated CrCl <50 mL/min while taking TDF/FTC as PrEP. (A2). Consider switching to TAF/FTC for MSM and for transgender women if CrCl >30 mL/min. (A3)
  - Does not adhere to HIV testing requirements. (A3)
- Clinicians should closely monitor patients who have chronic HBV for potential viral rebound when PrEP with TDF/FTC or TAF/FTC is discontinued and develop an alternative treatment plan if necessary. (A2)

Suspected Acute HIV

- For patients who present with any symptoms of acute retroviral illness and for whom acute HIV is suspected, clinicians should perform a plasma HIV RNA assay in conjunction with a laboratory-based 4th-generation HIV test. (A2)
- Clinicians should inform patients with suspected acute HIV about the increased risk of transmitting HIV during acute HIV infection. (A2)
- For patients who have a nonreactive HIV test result but have HIV RNA ≥5,000 copies/mL, a clinician can make a presumptive diagnosis of acute HIV, perform HIV genotype testing, and initiate ART that will be active against virus with potential mutations for tenofovir and emtricitabine (A2)
- For patients who have a nonreactive HIV test result but have detectable HIV RNA <5,000 copies/mL, clinicians should:
  - Perform repeat HIV RNA testing and repeat HIV diagnostic testing according to the CDC *Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens* to exclude a false-positive test result vs. a true-positive test result with a blunted viral response due to the presence of TDF/FTC or TAF/FTC. (A2)
  - Recommend initiation of an ART regimen that will be active against virus with potential mutations for tenofovir and emtricitabine while a definitive diagnosis is sought [c], unless suspicion for acute HIV is low. (A2)

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ALL RECOMMENDATIONS, *continued* P. 5

Asymptomatic Patients With a Reactive HIV Screening Test Result

- For asymptomatic patients who have a reactive HIV test result while using PrEP, clinicians should:
  - Ask about medication interruption of any duration and identify any access or adherence barriers. (A3)
  - Ask about potential risk exposures since the previous testing. (A*)
  - Ask about signs and symptoms of acute HIV since the previous visit. (A2)
  - Perform supplemental diagnostic testing according to the CDC HIV testing algorithm. (A1)
- If supplemental laboratory testing confirms HIV, clinicians should (A2):
  - Perform quantitative HIV RNA testing, if not already obtained as part of the diagnostic algorithm for suspected acute HIV, to measure viral load and perform genotypic resistance testing.
  - Recommend immediate initiation of ART that will be active against virus with potential mutations for tenofovir and emtricitabine; adjustments to the initial ART regimen can be made if indicated once genotypic resistance test results are available or if the patient experiences side effects [c].

Ambiguous Test Results

- The use of TDF/FTC or TAF/FTC as PrEP may alter viral load and immune response and cause ambiguous HIV test results using the current CDC HIV testing algorithm. In cases of ambiguous HIV test results, clinicians should consult with a care provider experienced in HIV and PrEP care [c] for guidance on appropriate next steps. (A3)
- If presumptive HIV treatment is initiated, clinicians should initiate ART that will be active against virus with potential mutations for tenofovir and emtricitabine. (A2)

Notes:

a. The FDA approved the use of TDF/FTC as PrEP on May 15, 2018, and the use of TAF/FTC as PrEP on October 3, 2019, for cisgender MSM and transgender women, including adolescents, weighing ≥35 kg (~77 lb) at high risk of acquiring HIV.

b. Indications for an HIV viral load test: Symptoms of acute HIV in the past 6 weeks or potential injection or sexual exposure in the past 4 weeks.

c. To consult an expert, call the NYSDOH AI CEI line at 1-866-637-2342.

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.

→ SELECTED KEY POINTS

Dosing Strategy

- Same-day initiation of PrEP is the goal whenever possible for appropriately selected patients, including for individuals who may be in the HIV testing window period.
- Daily dosing of PrEP is the preferred dosing regimen.
- On-demand PrEP with TDF/FTC is an option for cisgender MSM, although daily dosing is the preferred strategy based on robust existing data.
- On-demand dosing of TAF/FTC for PrEP has not been studied, and TAF/FTC should not be dosed in this way.
- On-demand PrEP is *not* recommended for: Transgender women who take estrogen or for individuals who engage in vaginal sex, use injection drugs, or have HBV.
- Use of PrEP only during discrete periods of risk is a reasonable alternative to ongoing daily PrEP when risk is episodic.

Time to Protection

- Time to protection is based on pharmacokinetic modeling studies and has not been clinically determined.
- For rectal exposure, protection against HIV acquisition is achieved after 7 days of TDF/FTC daily dosing and possibly earlier.
- For genital and blood exposures, protection against HIV acquisition is likely achieved after 7 days of TDF/FTC daily dosing, but optimal drug levels are achieved after 20 days of daily dosing.
- Taking 2 pills of TDF/FTC as PrEP on the day of initiation will decrease the time needed to achieve protective drug levels for all sites of exposure.
- Data are insufficient to make an estimate regarding time to protection for TAF/FTC.

Flexibility

- Flexibility regarding frequency of in-person visits may help improve PrEP uptake and persistence in care.
- Routine HIV testing is an integral component of the safe use of PrEP; HIV testing does not have to be linked to an in-office visit.
- If an individual taking PrEP misses a scheduled testing appointment, do not interrupt PrEP. Instead, encourage continuation of PrEP and work with the individual to reschedule any necessary visits and laboratory testing.
- Frequent screening for HIV infection is performed to prevent development of drug-resistant virus and to protect against transmission of HIV if HIV seroconversion has occurred.

Pregnancy

- Pregnancy is *not* a contraindication to TDF/FTC PrEP.
- The use of ARVs during pregnancy is monitored through the Antiretroviral Pregnancy Registry.
- Information regarding medications used during breastfeeding is available through the LactMed database.

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.