ALL RECOMMENDATIONS, continued

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 Rapid ART 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 daily dosing is a barrier to adherence or if episodic dosing is preferred. (A3) See Table 1: Recommended Dosing and Options for PrEP for additional information.
  - 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)

Table 2: Recommended Laboratory Tests to Support a Diagnosis of Acute HIV
- Evaluation of concomitant medications to identify nephrotoxic drugs or other contraindications to ART. (A3)
- Assessment to identify recent risk encounters (<72 hours) and the potential need for PEP prior to PrEP. (A3)
- Crush and urine spot testing for syphilis and gonococcal and chlamydial infections every 3 months at all sites of exposure, regardless of bearing potential at every visit. (A3)
- Urine glucose and protein. (B3)
- Serologic testing for syphilis. (C3)
- Chlamydia trachomatis antigen testing. (C3)
- Assessment of concomitant medications to identify nephrotoxic drugs or other contraindications to ART. (A3)
- Assessment to identify recent risk encounters (<72 hours) and the potential need for PEP prior to PrEP. (A3)
- Crush and urine spot testing for syphilis and gonococcal and chlamydial infections every 3 months at all sites of exposure, regardless of bearing potential at every visit. (A3)
- Urine glucose and protein. (B3)
- Serologic testing for syphilis. (C3)
- Chlamydia trachomatis antigen testing. (C3)

Prescription PrEP
- Clinicians should prescribe 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 other contraindications to ART. (A3)
  - Laboratory testing listed in Table 2: Recommended Laboratory Tests to Be Obtained Before Prescribing PrEP (see full guideline).
**ALL RECOMMENDATIONS, continued**

### 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:

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

### TDF/FTC VERSUS TAF/FTC AS PrEP

<table>
<thead>
<tr>
<th>TDF/FTC</th>
<th>TAF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness</strong></td>
<td>All populations.</td>
</tr>
<tr>
<td><strong>Renal safety</strong></td>
<td>Potential effect on renal tubular function. Meta-analysis shows good safety.</td>
</tr>
<tr>
<td></td>
<td>Discontinue if confirmed CrCl &lt;50 mL/min.</td>
</tr>
<tr>
<td><strong>Bone safety</strong></td>
<td>Potential decrease in bone mineral density. Meta-analysis shows good safety.</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>Weight neutral.</td>
</tr>
<tr>
<td><strong>LDL cholesterol</strong></td>
<td>Small decreases.</td>
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<tr>
<td><strong>Dosing</strong></td>
<td>Daily dosing is preferred. On-demand dosing is an option in cisgender MSM.</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Will go off patent in 2020.</td>
</tr>
</tbody>
</table>

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