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 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 ≥50 mL/min. (A3)
  - Does not adhere to HIV testing requirements. (A3)
- Clinicians should closely monitor patients who have chronic HBV for poten-
  tial 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
    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)

Pre-Transmission 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
    medications 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).

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).
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:
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 infection 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

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>TDF/FTC</th>
<th>TAF/FTC</th>
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<tbody>
<tr>
<td>All populations.</td>
<td>Cisgender MSM and transgender women [a].</td>
<td></td>
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<table>
<thead>
<tr>
<th>Renal safety</th>
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<tbody>
<tr>
<td>Potential effect on renal tubular function. Meta-analysis shows good safety.</td>
</tr>
<tr>
<td>Discontinue if confirmed CrCl &lt;50 mL/min.</td>
</tr>
<tr>
<td>Improved renal biomarkers compared to TDF.</td>
</tr>
<tr>
<td>Can be used with stage 3 CKD (CrCl 30–50 mL/min).</td>
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<tr>
<th>Bone safety</th>
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<tr>
<td>Potential decrease in bone mineral density. Meta-analysis shows good safety.</td>
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<tr>
<td>Favorable bone biomarkers compared with TDF.</td>
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<tr>
<th>Weight</th>
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<tbody>
<tr>
<td>Weight neutral.</td>
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<td>Mild weight gain observed in studies.</td>
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<tr>
<th>LDL cholesterol</th>
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<tr>
<td>Small decreases.</td>
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<td>Small increases.</td>
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<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td>Daily dosing is preferred. On-demand dosing is an option in cisgender MSM.</td>
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<tr>
<td>Daily dosing only.</td>
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<th>Cost</th>
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<tr>
<td>Will go off patent in 2020.</td>
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<td>Currently similar to TDF/FTC.</td>
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a. Transgender women made up only 1% of the DISCOVER study population.