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- Clinicians should counsel patients with seronegative partners about the reduction of HIV transmission risk after effective ART is initiated and viral suppression is achieved, and should strongly recommend ART for patients with seronegative partners. (A1)
- Clinicians should evaluate and prepare patients for ART initiation as soon as possible; completion of the following should not delay initiation: Discuss benefits and risks of ART with the patient (A3); assess patient readiness (A3); and identify and ameliorate factors that might interfere with successful adherence to treatment, including inadequate access to medication, inadequate supportive services, psychosocial factors, active substance use, or mental health disorders (A2).
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WHEN TO INITIATE ANTIRETROVIRAL THERAPY, WITH PROTOCOL FOR RAPID INITIATION

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE

AUGUST 2022

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Rapid Initiation of ART Checklists

**Counseling**

- Ensuring the patient knows how to reach the care team
- Following through with clinic visits
- Identifying and addressing psychosocial issues that may pose barriers to treatment
- Referring for substance use and behavioral health counseling if indicated
- Referring for housing assistance if indicated
- Ensuring the patient knows how to reach the care team if needed, to address adverse effects of medications or other concerns.

**Medical History**

- When taking a medical history before rapid ART initiation, ask about:
  - Date and result of last HIV test.
  - Serostatus of sex partners and their ART regimens if known.
  - Previous use of antiretroviral medications, including as PrEP or PEP, with dates of use.
  - Comorbidities, including a history of renal or liver disease, particularly hepatitis B infection.
  - Prescribed and over-the-counter medications.
  - Drug allergies.
  - Substance use.
  - Symptoms, to assess for active cryptococcal and tuberculosis meningitis.
  - Psychiatric history, particularly depressive or psychotic symptoms or any history of suicidality.
  - Possible pregnancy and childbearing plans in individuals of childbearing potential.

**Baseline Laboratory Testing**

- ART can be initiated while awaiting test results.
  - HIV-1/2 antigen/antibody assay.
  - HIV quantitative viral load.
  - Baseline HIV genotypic resistance profile.
  - Baseline CD4, cell count.
  - Testing for hepatitis A, B, and C viruses.
  - Comprehensive metabolic panel (creatinine clearance, hepatic profile).
  - Sexually transmitted infection (STI) screening; see the NYSDOH AI STI Care Guidelines.
  - Urinalysis.
  - Pregnancy test for individuals of childbearing potential.

### Table 1: Preferred and Alternative Regimens for Rapid ART Initiation in Nonpregnant Adults

<table>
<thead>
<tr>
<th>Regimen (rating)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td></td>
</tr>
<tr>
<td>TAF/FTC should not be used in patients with CrCl &lt;30 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Contains 25 mg of TAF, unboosted.</td>
<td></td>
</tr>
<tr>
<td>Magnesium– or aluminum–containing antacids may be taken 2 hours before or 6 hours after BIC; calcium–containing antacids or iron supplements may be taken simultaneously if taken with food.</td>
<td></td>
</tr>
<tr>
<td>TAF 25 mg/FTC and DTG [A1] (Descovy and Tivicay)</td>
<td>Available as a single-tablet formulation, taken once daily.</td>
</tr>
<tr>
<td>TAF/FTC should not be used in patients with CrCl &lt;30 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Contains 25 mg of TAF, unboosted.</td>
<td></td>
</tr>
<tr>
<td>Two tablets once daily.</td>
<td></td>
</tr>
<tr>
<td>Magnesium– or aluminum–containing antacids may be taken 2 hours before or 6 hours after DTG; calcium–containing antacids or iron supplements may be taken simultaneously if taken with food.</td>
<td></td>
</tr>
<tr>
<td>TAF 10 mg/FTC/DRV/COBI [A2] (Symtuza)</td>
<td>Available as a single-tablet formulation, taken once daily.</td>
</tr>
<tr>
<td>TAF/FTC should not be used in patients with CrCl &lt;30 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Contains 10 mg TAF, boosted.</td>
<td></td>
</tr>
<tr>
<td>TAF/FTC should not be used in patients with CrCl &lt;30 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Pay attention to drug–drug interactions.</td>
<td></td>
</tr>
<tr>
<td><strong>Regimen for Patients With Exposure to TDF/FTC as PrEP Since Their Last Negative HIV Test</strong></td>
<td></td>
</tr>
<tr>
<td>DTG/DRV/COBI/TAF 10 mg/FTC [A3] (Tivicay and Symtuza)</td>
<td>TAF/FTC should not be used in patients with CrCl &lt;30 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
</tr>
<tr>
<td>Documented DTG resistance after initiation in treatment-naïve patients is rare.</td>
<td></td>
</tr>
<tr>
<td>Magnesium– or aluminum–containing antacids may be taken 2 hours before or 6 hours after DTG; calcium–containing antacids or iron supplements may be taken simultaneously if taken with food.</td>
<td></td>
</tr>
<tr>
<td>TTDF may be substituted for TAF; TDF/FTC is available as a single tablet (brand name, Truvada).</td>
<td></td>
</tr>
<tr>
<td>3TC may be substituted for FTC.</td>
<td></td>
</tr>
<tr>
<td>3TC/TDF is also available as a single tablet.</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2: Preferred Regimens for Rapid ART Initiation in Pregnant Adults

See also: DHHS: Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States.

<table>
<thead>
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<th>Regimen (rating)</th>
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<tr>
<td>TDF/FTC and DTG [A1] (Truvada and Tivicay)</td>
<td>Should not be initiated during the first trimester (&lt;14 weeks), gestational age measured by last menstrual period.</td>
</tr>
<tr>
<td>TDF/FTC should not be used in patients with CrCl &lt;50 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Magnesium– or aluminum–containing antacids may be taken 2 hours before or 6 hours after DTG, calcium–containing antacids or iron supplements may be taken simultaneously if taken with food.</td>
<td></td>
</tr>
<tr>
<td>TDF/FTC and ATV and RTV [A2] (Truvada and Reyataz and Norvir)</td>
<td>TDF/FTC should not be used in patients with CrCl &lt;50 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
</tr>
<tr>
<td>Carefully consider drug–drug interactions with RTV.</td>
<td></td>
</tr>
<tr>
<td>Scleral icterus from benign hyperbilirubinemia due to ATV may be a patient concern.</td>
<td></td>
</tr>
<tr>
<td>The recommended dose of ATV is 300 mg once daily in the first trimester; the dose increases to 400 mg once daily in the second and third trimesters when used with either TDF or a histamine–2 receptor antagonist.</td>
<td></td>
</tr>
<tr>
<td>This regimen can be initiated in the first trimester.</td>
<td></td>
</tr>
<tr>
<td>TDF/FTC and DRV/RTV [A2] (Truvada and Prezista and Norvir)</td>
<td>Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy.</td>
</tr>
<tr>
<td>TDF/FTC should not be used in patients with CrCl &lt;50 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
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</tr>
<tr>
<td>Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy.</td>
<td></td>
</tr>
<tr>
<td>Regimen can be initiated in the first trimester.</td>
<td></td>
</tr>
<tr>
<td>TDF/FTC and RAL [A2] (Truvada and Isentress)</td>
<td>RAL 400 mg twice daily is recommended in pregnancy, not once daily RAL HD.</td>
</tr>
<tr>
<td>TDF/FTC should not be used in patients with CrCl &lt;50 mL/min; re-evaluate after baseline laboratory testing results are available.</td>
<td></td>
</tr>
<tr>
<td>Administer as TDF/FTC once daily and RAL 400 mg twice daily.</td>
<td></td>
</tr>
<tr>
<td>The recommended dose of RAL is 400 mg twice daily without regard to food.</td>
<td></td>
</tr>
<tr>
<td>This regimen can be initiated in the first trimester.</td>
<td></td>
</tr>
</tbody>
</table>

### Medications to Avoid

- ABC should be avoided unless a patient is confirmed to be HLA-B*5701 negative.
- RPV should be administered only in patients confirmed to have a CD4 cell count ≥200 cells/µL and a viral load <100,000 copies/mL.
- EFV is not as well tolerated as other antiretroviral medications, and nonnucleoside reverse transcriptase inhibitors have higher rates of resistance.

### Drug name abbreviations:

- 3TC, lamivudine; ABC, abacavir; ATV, atazanavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EFV, efavirenz; FTC, emtricitabine; RAL, raltegravir; RTV, ritonavir; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.