When to Initiate Antiretroviral Therapy, with Protocol for Rapid Initiation

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE

ALL RECOMMENDATIONS

- Clinicians should recommend ART to all patients with HIV infection. (A1)
- Clinicians should offer rapid initiation of ART—preferably on the same day (A1) or within 72 hours—to all individuals who are candidates for rapid ART initiation (see full guideline text) and who have a confirmed HIV diagnosis (A1), a reactive HIV screening test result pending results of a confirmatory HIV test (A2), or suspected acute HIV infection, i.e., HIV antibody negative and HIV RNA positive (A2).
- 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).
- Clinicians should refer patients for supportive services as necessary to address modifiable barriers to adherence. An ongoing plan for coordination of care should be established. (A3)
- Clinicians should involve patients in the decision-making process regarding initiation of ART and which regimen is most likely to result in adherence. The patient should make the final decision of whether and when to initiate ART. (A3)
- If the patient understands the benefits of rapid initiation but declines ART, then initiation should be revisited as soon as possible.

RESOURCES

- The CEI Line provides primary care providers in New York State the opportunity to consult with clinicians who have experience managing ART. The CEI Line can be reached at 1-866-637-2342 or 1-585-273-2793.
- The AIDS Institute maintains a voluntary NYSDOH AIDS Institute Provider Directory to assist with identification of experienced providers in New York State.

NYSDOH Uninsured Care Programs

Hours of operation: Monday – Friday, 8:00 AM to 5:00 PM
Call: In state, toll free: 1-800-542-2437 or 1-844-682-4058; out of state: (518) 459-1641; TDD: (518) 459-0121
Address: Empire State, P.O. Box 2052, Albany, NY 12220-0052

GOOD PRACTICES

- For patients with a reactive HIV antibody screening test that is pending confirmation, make sure the patient understands the benefits of rapid ART initiation and the following:
  1. Reactive screening test results are not formally diagnostic, because false-positive results are still possible;
  2. A confirmatory (diagnostic) HIV test will be performed;
  3. ART will be discontinued if the confirmatory test result is negative and continued if it is positive;
  4. The benefit of starting ART early, after a presumptive positive screening test, outweighs the negligible risk of taking ART for a few days and then stopping it if confirmed HIV negative.
- Provide the result of the confirmatory HIV test as soon as it is available; discontinue ART if the result is negative and reinforce adherence and next steps if it is positive.
- If a patient declines rapid ART initiation, discuss options for deferred initiation of ART, link the patient with HIV primary care, and outline next steps.
- Follow up within 24 to 48 hours, by telephone or another preferred method, with a patient who has initiated ART to assess medication tolerance and adherence.
- If feasible, schedule an in-person visit for 7 days after ART initiation.
Referring for substance use and behavioral health

Assessing health literacy.

Following through with clinic visits.

Recognizing and responding to side effects.

Managing disclosure, if indicated.

Priorities for counseling and education:

- Confirming the diagnosis of HIV.
- Managing disclosure, if indicated.
- Adhering to the ART regimen.
- Recognizing and responding to side effects.
- Following through with clinic visits.
- Assessing health literacy.
- Managing lifelong ART: Navigating acquisition of and
  paying for medications required for lifelong therapy,
  including pharmacy selection, insurance requirements
  and restrictions, co-pays, and prescription refills.
- 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.

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 cryptoccocal 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.

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

<table>
<thead>
<tr>
<th>Regimen (rating)</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td></td>
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</table>
| TAF 25 mg/FTC/BIC [A1] (Biktarvy) | - Available as a single-tablet formulation, taken once daily.
  - TAF/FTC should not be used in patients with a CrCl < 30 mL/min; re-evaluate after baseline laboratory testing results are available.
  - Contains 25 mg of TAF, unboosted.
  - 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. |
| TAF 25 mg/FTC and DTG [A1] (Descovy and Tivicay) | - TAF/FTC should not be used in patients with CrCl < 30 mL/min; re-evaluate after baseline laboratory testing results are available.
  - Contains 25 mg of TAF, unboosted.
  - Two tablets once daily.
  - 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. |
| TDF 10 mg/FTC/DRV-COB [A2] (Symtuza) | - Available as a single-tablet formulation, taken once daily.
  - Contains 10 mg TAF, boosted. |
| **Alternative**   |          |
| TAF 25 mg/FTC and RAL HD [B1] (Descovy and Isentress HD) | - TAF/FTC should not be used in patients with CrCl < 30 mL/min; re-evaluate after baseline laboratory testing results are available.
  - To date, no clinical trials have been conducted with TAF and RAL; data are based on bioequivalence pharmacokinetic studies.
  - Contains 25 mg of TAF, unboosted.
  - Administer as TAF/once daily and RAL HD 1200 mg once daily, dosed as two 600 mg HD tablets.
  - Magnesium- or aluminum-containing antacids are contraindicated; coadministration of calcium-containing antacids is not recommended with RAL HD. |

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

See also: DHHS: Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infections and Interventions to Reduce Perinatal HIV Transmission in the United States.

<table>
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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>
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<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>
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<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 and RAL [A2] (Truvada and Isentress)</td>
<td>- RAL 400 mg twice daily is recommended in pregnancy, not once daily RAL HD.</td>
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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.

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/mm³ 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.