HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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WHEN TO INITIATE ANTIRETROVIRAL THERAPY, WITH PROTOCOL FOR RAPID INITIATION

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE JANUARY 2020

ALL RECOMMENDATIONS P.1

- 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 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.

ALL RECOMMENDATIONS *(continued from P.1)* **P.2**

- In patients with advanced HIV (or AIDS), ART should be initiated even if barriers to adherence are present. In these cases, referrals to specialized adherence programs should be made for intensified adherence support. (A2)
- After ART has been initiated, response to therapy should be monitored by, or in consultation with, a clinician with experience in managing ART. (A2)

Protocol for Rapid ART Initiation

- To determine whether a patient is a candidate for rapid ART initiation, the clinician should confirm that the individual has any of the following (A1):
  - A reactive point-of-care HIV test result, or confirmed HIV diagnosis, or suspected acute HIV infection, or known HIV infection, and
  - No prior ART (i.e., treatment-naive) or limited prior use of antiretroviral medications, and
  - No medical conditions or opportunistic infections that require deferral of rapid ART initiation, including suspected cryptococcal or tuberculous meningitis.
- Clinicians should perform baseline laboratory testing listed for all patients who are initiating ART immediately; ART can be started while awaiting laboratory test results. (A3)

General Principles in Choosing a Regimen for Rapid ART Initiation

- Clinicians should involve their patients when deciding which ART regimen is most likely to result in adherence. (A3)
- Before initiating ART, clinicians should:
  - Assess the patient's prior use of antiretroviral medications, including pre-exposure prophylaxis (PrEP), which may increase the risk for baseline resistance. (A2)
  - Assess for any comorbidities and chronic coadministered medications that may affect the choice of regimen for initial ART. (A2)
  - At the time of HIV diagnosis, obtain genotypic resistance testing for the protease (A2), reverse transcriptase (A2), and integrase (B2) genes.
  - Ask individuals of childbearing potential about the possibility of pregnancy, their reproductive plans, and their use of contraception. (A3)

ALL RECOMMENDATIONS *(continued from P.2)* **P.3**

General Principles in Choosing a Regimen for Rapid ART Initiation, *continued*

- For ART-naive patients, clinicians should select an initial ART regimen that is preferred; see *Table 1: Preferred and Alternative Regimens for Rapid ART Initiation in Nonpregnant Adults*. (A1)
- Clinicians should reinforce medication adherence regularly. (A3)
- Clinicians should obtain a viral load test 4 weeks after ART initiation to assess the response to therapy. (A3) See the NYSDOH AI guideline *Virologic and Immunologic Monitoring* for more information.

Notes:

- For recommendations on initiating ART in long-term nonprogressors, elite controllers, and patients with acute opportunistic infections, see the full guideline.
- Initial ART regimens for patients with chronic hepatitis B must include NRTIs that are active against hepatitis B. See the NYSDOH AI guideline *HBV-HIV Coinfection*.
- In co-infected patients with hepatitis C virus (HCV), attention should be paid to interactions between the planned ART and HCV therapy.

KEY POINTS

- Rapid ART initiation, the standard of care in New York State, is efficacious, safe, and highly acceptable, with few patients declining the offer of immediate ART.
- Patients with active substance use, untreated mental health conditions, immigration issues, or unstable housing deserve the highest standard of HIV care, including the option of rapid initiation of ART. Potential barriers to medication adherence and care continuity can be addressed with appropriate counseling and linkage to support services.
- Patients with a new reactive HIV test result can be retested using a second point-of-care test from a different manufacturer than that of the first test, if available, to minimize the possibility of a false-positive result.
  - See the NYSDOH AI guideline *HIV Testing > Characteristics of FDA-Approved Rapid HIV Tests* for a list of available point-of-care HIV tests.

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.

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 Station, P.O. Box 2052, Albany, NY 12220-0052

Rapid Initiation of ART Checklists

Counseling

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.

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

Regimen (rating)	Comments
Preferred	
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. • See DTG safety statement in full guideline, www.hivguidelines.org.
TAF 10 mg/FTC/DRV/COBI [A2] (Symtuza)	• Available as a single-tablet formulation, taken once daily. • Contains 10 mg TAF, boosted. • TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Pay attention to drug-drug interactions.
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/FTC 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.
Regimen for Patients With Exposure to TDF/FTC as PrEP Since Their Last Negative HIV Test	
DTG/DRV/COBI/TAF 10 mg/FTC [A3] (Tivicay *and* Symtuza)	• TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • Documented DTG resistance after initiation in treatment-naive patients is rare. • 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 may be substituted for TAF; TDF/FTC is available as a single tablet (brand name Truvada). • 3TC may be substituted for FTC. • 3TC/TDF is also available as a single tablet. • See DTG safety statement in full guideline, www.hivguidelines.org.
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/mm^3 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.	

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.

Regimen (rating)	Comments
TDF/FTC *and* DTG [A1] (Truvada *and* Tivicay)	• Should not be initiated during the first trimester (<14 weeks), gestational age measured by last menstrual period. • TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • 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. • See DTG safety statement in full guideline, www.hivguidelines.org.
TDF/FTC *and* ATV *and* RTV [A2] (Truvada *and* Reyataz *and* Norvir)	• TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Carefully consider drug-drug interactions with RTV. • Scleral icterus from benign hyperbilirubinemia due to ATV may be a patient concern. • 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. • This regimen can be initiated in the first trimester.
TDF/FTC *and* DRV/RTV [A2] (Truvada *and* Prezista *and* Norvir)	• Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy. • TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended in pregnancy. • Regimen can be initiated in the first trimester.
TDF/FTC *and* RAL [A2] (Truvada *and* Isentress)	• RAL 400 mg twice daily is recommended in pregnancy, *not* once daily RAL HD. • TDF/FTC should not be used in patients with CrCl <50 mL/min; re-evaluate after baseline laboratory testing results are available. • Administer as TDF/FTC once daily and RAL 400 mg twice daily. • The recommended dose of RAL is 400 mg twice daily without regard to food. • This regimen can be initiated in the first trimester.

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.

← 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 *When to Initiate ART, With Protocol for Rapid Initiation.* The full guideline is available at www.hivguidelines.org.