HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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RAPID ART INITIATION

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE FEBRUARY 2023

ALL RECOMMENDATIONS P.1

Rationale for Rapid ART Initiation

- Clinicians should recommend ART to all patients with a diagnosis of 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 acute HIV infection, i.e., are HIV antibody negative and HIV RNA positive (A2).
- Clinicians should counsel patients with HIV-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 HIV-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, the clinician should revisit the topic of initiation as soon as possible.
- Clinicians should initiate ART in patients with advanced HIV (or AIDS) 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, the clinician should monitor the patient's response to therapy or consult with an experienced HIV care provider. (A2)

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

Counseling and Education Before Initiating ART

- Clinicians should counsel and educate patients regarding the following:
  - Basic information about HIV, CD4 cell count, viral load, and resistance (A3)
  - Available treatment options and potential risks and benefits of therapy (see text in full guideline) (A3)
  - Optimal adherence requirements to avoid development of viral drug resistance (A2)
  - Use of safer-sex practices during the first 6 months after ART is started or until the patient's viral load is suppressed, to prevent HIV transmission or superinfection (A3)
- Clinicians should involve the patient in the decision-making process regarding initiation of ART. (A3)

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 (A1):
  - A new reactive point-of-care HIV test result, a confirmed HIV diagnosis, suspected acute HIV infection, or known HIV infection, *and*
  - No prior ART (i.e., treatment naïve, excluding PrEP and PEP) or limited prior use of ARVs, *and*
  - No medical conditions or specific opportunistic infections that require deferral of ART initiation, including suspected cryptococcal or TB meningitis and CMV retinitis
- Clinicians should perform baseline laboratory testing listed in Box 2 in full guideline 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 ARVs, including as 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 *cont.*

- For ART-naïve 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)

Notes:

- For recommendations on initiating ART in long-term nonprogressors, elite controllers, and patients with acute opportunistic infections, see the full guideline.
- For recommendations on initiating ART in pregnant women with HIV, refer to the DHHS.
- Initial ART regimens for patients with chronic HBV infection must include NRTIs that are active against HBV.
- In patients with HIV/HCV coinfection, attention should be paid to interactions between 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 ART initiation. 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 verify the result.

GOOD PRACTICES

- Ensure that patients with a reactive HIV antibody screening test that is pending confirmation understand the benefits of rapid ART initiation, as well as the following:
  - Reactive screening test results are not formally diagnostic, because false-positive results are still possible.
  - A confirmatory (diagnostic) HIV test will be performed.
  - ART will be discontinued if the confirmatory test result is negative and continued if it is positive.
  - 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.

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: 1-518-459-1641
Address: Empire Station, P.O. Box 2052, Albany, NY 12220-0052

Rapid Initiation of ART Checklists

Counseling

Priorities for patient education and counseling:

- Confirming the diagnosis of HIV
- Managing disclosure, if indicated
- Adhering to the ART regimen
- Ensuring the patient knows how to reach the care team to address any potential adverse effects of medications or other concerns
- Following through with clinic visits
- Assessing health literacy
- Navigating acquisition of and paying for medications required for lifelong therapy, including pharmacy selection, insurance requirements and restrictions, copays, 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

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 ARVs, including as PrEP or PEP, with dates of use
- Comorbidities, including a history of renal or liver disease, particularly HBV infection
- Prescribed and over-the-counter medications
- Drug allergies
- Substance use
- Any signs or symptoms of active cryptococcal or TB meningitis, or visual changes associated with CMV retinitis
- 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 Ag/Ab immunoassay
- HIV quantitative viral load test
- Baseline HIV genotypic resistance profile
- Baseline CD4 cell count
- Testing for hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)
- Pregnancy test for individuals of childbearing potential
- Urinalysis
- Syphilis, gonorrhea, and chlamydia screening as per CDC guidelines

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

Regimen [rating]	Comments
Preferred Regimens for Patients Not on PrEP	
TAF 25 mg/FTC/BIC [A1] (Biktarvy)	• TAF/FTC/BIC is 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. • This regimen 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. • This regimen contains 25 mg of TAF, unboosted. • Administer as 2 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. • Documented DTG resistance after initiation in treatment-naive patients is rare.
TAF 10 mg/FTC/DRV/COBI [A2] (Symtuza)	• TAF/FTC/DRV/COBI is available as a single-tablet formulation, taken once daily. • This regimen 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.
Regimens for Patients Who Have Taken TDF/FTC as PrEP Since Their Last Negative HIV Test	
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. • 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 available as a single tablet (brand name Cimduo).
TAF 25 mg/FTC/BIC [A1] (Biktarvy)	• TAF/FTC/BIC is available as a single-tablet formulation, taken once daily. • TAF/FTC should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. • This regimen 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 10 mg/FTC/DRV/COBI [B2] (Symtuza)	• TAF/FTC/DRV/COBI is available as a single-tablet formulation, taken once daily. • This regimen 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.
Regimen for Patients Who Have Taken CAB LA as PrEP Within the Previous 14 Months	
TAF 10 mg/FTC/DRV/COBI [A2] (Symtuza)	• TAF/FTC/DRV/COBI is available as a single-tablet formulation, taken once daily. • This regimen 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.
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 ARVs, and NNRTIs have higher rates of resistance than other classes. • DTG/3TC requires baseline resistance testing and is not recommended when HBV status is unknown.	

ABBREVIATIONS

3TC, lamivudine; ABC, abacavir; Ag/Ab, antigen/antibody; ART, antiretroviral therapy; ARV, antiretroviral medication; BIC, bictegravir; CAB LA, long-acting injectable cabotegravir; COBI, cobicistat; CrCl, creatinine clearance; DRV, darunavir; DTG, dolutegravir; EFV, efavirenz; FTC, emtricitabine; HBV, hepatitis B virus; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PrEP, pre-exposure prophylaxis; RPV, rilpivirine; STI, sexually transmitted infection; 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 *Rapid ART Initiation*. The full guideline is available at www.hivguidelines.org.