ALL RECOMMENDATIONS

Please see full guideline for additional information

- Clinicians should offer rapid initiation of ART—preferably on the same day (A1) or within 96 hours—to all individuals who are candidates for rapid ART initiation and who have:
  - Confirmed HIV diagnosis (A1), *or*
  - 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)
- 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 new reactive point-of-care HIV test result, or new confirmed HIV diagnosis, or acute HIV infection, or known HIV infection *and*
  - No prior ART (i.e., treatment naïve) 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 in *Box 3: Baseline Laboratory Testing Checklist*, for all patients who are initiation ART immediately; ART can be started while awaiting laboratory test results. (A3)
- 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 PrEP, as this 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)
  - Obtain testing for genotypic resistance for the protease and reverse transcriptase genes at time of HIV diagnosis. (A2)
  - Ask individuals of childbearing potential about the possibility of pregnancy, their reproductive plans, and the use of contraception. (A3)
- 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)
  - See the NYSDOH AI guideline *Virologic and Immunologic Monitoring* for more information.

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 that:
  1. Screening test results are not diagnostic, because a false-positive result is 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, if it is needed, 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; reinforce adherence and next steps if it is positive.
- If a patient declines rapid ART initiation, discuss options for deferred initiation of ART and linkage 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.

KEY POINT

- Patients with a new reactive HIV test result can be retested using a second point-of-care test, preferably from a different manufacturer than that of the first test, 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.

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

← 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 Initiation of ART*. The full guideline is available at www.hivguidelines.org.

HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

VISIT **HIVGUIDELINES.ORG** TO LEARN MORE OR VIEW COMPLETE GUIDE

RAPID ART INITIATION

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE JULY 2019

Rapid Initiation of ART Checklists: Counseling, Medical History, and Laboratory Testing

COUNSELING

Priorities for counseling and education before rapid ART initiation:

- ❍ Confirming HIV diagnosis.
- ❍ Managing disclosure.
- ❍ Adhering to the ART regimen.
- ❍ Recognizing and responding to side effects as they occur.
- ❍ Following through with clinic visits.
- ❍ Assessing health literacy.
- ❍ Navigating acquisition of and payment for medications: Pharmacy selection, insurance requirements and restrictions, co-pays, and refills.
- ❍ Identifying and addressing psychosocial barriers to treatment.
- ❍ Establishing the best methods of contact.
- ❍ Ensuring the patient knows how to reach the care team.
- ❍ Referrals, if indicated: Substance use treatment; behavioral health counseling; housing assistance

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 and dates of antiretroviral medications, including PrEP or repeated episodes of taking PEP.
- ❍ 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 TB 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).
- ❍ STI screening; see the NYSDOH AI *STI Care Guidelines*.
- ❍ Urinalysis.
- ❍ Pregnancy test for individuals of childbearing potential.

Figure 1: Protocol for Rapid Antiretroviral Therapy Initiation

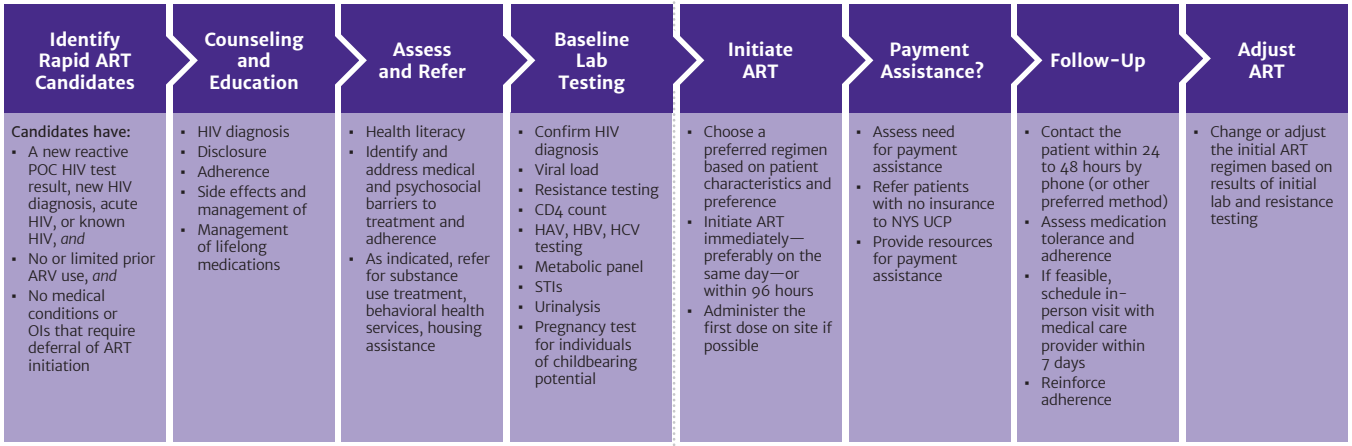

TABLE 1: Preferred and Alternative Regimens for Rapid ART Initiation in Nonpregnant Adults

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 CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. · Contains 25 mg of TAF, unboosted. · Take magnesium- or aluminum-containing antacids 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. · Take magnesium- or aluminum-containing antacids 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/COBI/DRV [A2] (Symtuza)	· 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. · 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 *and* 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. · This initial ART regimen may be simplified based on results of genotypic resistance testing. · Documented DTG resistance after initiation in treatment-naive patients is rare. · Take magnesium- or aluminum-containing antacids 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. [A2] · RPV should be administered only in patients confirmed to have a CD4 cell count ≥200 cells/mm^3 and viral load <100,000 copies/mL. [A2] · EFV is not as well tolerated as other antiretroviral medications, and NNRTIs have higher rates of resistance. [A2]	

Drug name abbreviations: ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EFV, efavirenz; FTC, emtricitabine; RAL, raltegravir; RPV, rilpivirine; TAF, tenofovir alafenamide.

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. · Take magnesium- or aluminum-containing antacids 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/r 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/r 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: 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.