

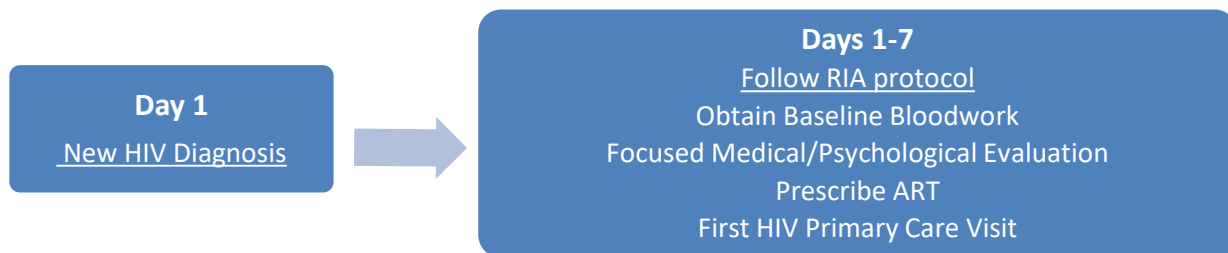
# The New Standard: Treatment Initiation at Time of HIV Diagnosis

## Provider FAQ

Early diagnosis of HIV infection, followed by prompt antiretroviral therapy (ART) initiation, expands the concept of universal ART. There are clear clinical benefits in reducing morbidity and mortality for patients with HIV and decreasing HIV transmission to their sexual partners.<sup>1</sup> The shortened time frame between diagnosis and treatment allows the newly diagnosed patient to immediately begin effective treatment, improve their health and start protecting their partners. A person with a sustained undetectable HIV viral load is healthier and cannot transmit HIV.

### 1. What is RIA (rapid initiation of ART)

RIA is the New York State Department of Health (NYSDOH) initiative developed in response to the [AIDS Institute's 2019 "Call to Action" letter](#) that emphasized the importance of starting ART at the time of HIV diagnosis. All HIV service providers in New York State (NYS) are expected to develop policies and procedures to ensure any person in NYS, found to be living with HIV, would have the option of starting HIV treatment without delay.



### 2. Why is RIA important?

- **Improved individual health outcomes<sup>2, 3, 4</sup>**

Clinical pilots in New York City (NYC) and San Francisco showed that patients achieve viral load suppression more quickly than those started on a “standard treatment” timeline and at the end of one year, patients in the rapid initiation group were more likely to remain engaged in care.

- **Supported by evidence-based recommendations:**

The NYSDOH Clinical Guidelines, US Department of Health and Human Services (DHHS), World Health Organization, and the International Antiviral Society-USA (IAS-USA) all advise prompt ART initiation regardless of CD4+ T cell count.

- **Patients want this option:**

Data from clinics in NYS and San Francisco show that over 75% of patients accepted the option of expedited treatment. Participants also reported that same day treatment eliminates a potentially stressful waiting period and reduces barrier to initiation of HIV care.

### 3. What is the evidence supporting immediate ART?

Pilot studies in the United States and randomized controlled trials in resource-limited settings show rapid ART initiation reduces the time to linkage to care and viral load suppression. The START (“Strategic Timing of Antiretroviral Treatment”) study is a randomized, controlled clinical trial of “immediate” (CD4>500) vs. “deferred” (CD4 ≤ 350) ART, designed to more clearly define the optimal time for HIV- infected individuals to begin ART.<sup>5</sup> The study found that the risk of developing serious illness or death was 53% lower in the early treatment group than in the deferred treatment group. Additionally, rates of serious AIDS related events and serious non-AIDS related events were lower in the early treatment group than in the deferred treatment group.

<sup>1</sup> <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/10/initiation-of-antiretroviral-therapy>

<sup>2</sup> Rosen S et al. Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapiT Randomized Controlled Trial. PLoS Med. 2016;13(5): e1002015.

<sup>3</sup> Koenig SP et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. PLoS Med. 2017; 14(7): e1002357.

<sup>4</sup> Amaniyre G, Semitala FC, Namusobya J, et al. Effects of a multicomponent intervention to streamline initiation of antiretroviral therapy in Africa: a stepped-wedge cluster-randomised trial. Lancet HIV. 2016;3(11): e539-e548.

<sup>5</sup> Insight Start Study Group, Lundgren JD, Babiker AG, et al. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. 2015; 373:795-807

Immediate ART protocols have been piloted in various U.S. clinics<sup>6, 7,8</sup>, and initiating ART at the time of HIV diagnosis has become standard of care in several clinics and jurisdictions, including San Francisco (under the municipal Getting to Zero initiative) and NYC (in the NYC Department of Health and Mental Health Sexual Health Clinics). The USA-IAS guidelines affirm “ART should be initiated as soon as possible after diagnosis, including immediately after diagnosis, unless [the] patient is not ready to commit to starting therapy.” The rating of A1a indicates strong support for the recommendation.<sup>9</sup>

#### 4. When should RIA be offered?

ART should be initiated as soon as possible after diagnosis, even beginning treatment the same day as diagnosis, unless the patient is not ready to commit to starting therapy<sup>10</sup>. A newly diagnosed patient who is interested in immediate treatment may be started on treatment based on a single reactive HIV rapid test result. If available, a second reactive test from a different manufacturer or based on a different rapid test technology will increase provider confidence in the initial result but is not required. If both tests are reactive, it is extremely unlikely that this is a false-positive and the provider can share that information with the patient.

If agency policy requires laboratory verification before starting treatment, obtain baseline laboratory tests along with a confirmatory HIV 1/2 antigen/antibody assay. Discuss the option of rapid treatment and schedule an intake/medication initiation appointment as soon as the laboratory-based HIV diagnostic test results are available.

#### 5. Is RIA safe?

Yes. The initial regimens suggested for RIA are safe, well-tolerated, and likely to achieve viral suppression even in the setting of limited drug resistance. **It is important for providers to emphasize that immediate ART is safe, effective and begins to decrease viral load while the results of screening genotype are still pending.**

#### 6. Is RIA an option for patients of transgender experience who are newly diagnosed with HIV?

Yes, although there are limited data on interactions between ART and gender affirming hormones, hormone therapy is not a contradiction to treatment of HIV. The RIA protocol should be followed, and the suggested initial regimens can be used. If the patient is taking feminizing hormones, monitor estradiol levels after initiating ART. Support adherence to ART by addressing changes in estrogenic symptoms. A 2017 study<sup>11</sup> of transgender women living with HIV showed that they may not take ART as prescribed if ART is perceived as interfering with hormone therapy. There are limited data on the interactions between ART and masculinizing hormones or other drugs used as anti-androgens for feminization. Currently, there are no documented interactions between ART and either androgens (e.g., testosterone) or anti-androgens (e.g., spironolactone).

#### 7. Who is eligible for RIA?

- Individuals with a new HIV diagnosis and no known contraindications:
  - Those with a **reactive point-of-care (POC) HIV test**, or
  - Those with a **positive result from a lab-based HIV test**, or
  - Those who are identified as **previously diagnosed** and:
    - have never been in care, or
    - are treatment naïve
- Patients with a history of limited ART use (e.g., stopped first-line therapy for reasons other than regimen failure) if concern for acquired resistance is low. (requires a case-by- case determination)

<sup>6</sup> Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting. *J Acquir Immune Defic Syndr*. 2017 Jan 1;74(1):44-51.

<sup>7</sup> Ford N, Migone C, Calmy A, et al. Benefits and risks of rapid initiation of antiretroviral therapy. *AIDS*. Jan 2, 2018; 32(1):17-23.

<sup>8</sup> Colasanti J, Sumitani J, Mehta CC, et al. Implementation of a Rapid Entry Program Decreases Time to Viral Suppression Among Vulnerable Persons Living with HIV in the Southern United States. *Open Forum Infect Dis*. 2018 Jun 28;5(6).

<sup>9</sup> Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2018 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2018;320(4):379-396

<sup>11</sup> Braun HM, Candelario J, Hanlon CL, et al. Transgender Women Living with HIV Frequently Take Antiretroviral Therapy and/or Feminizing Hormone Therapy Differently Than Prescribed Due to Drug-Drug Interaction Concerns. *LGBT Health*. 2017;4(5):371–375. doi:10.1089/lgbt.2017.0057

**8. When should rapid ART be deferred?**

There are certain medical conditions which should be addressed before starting RIA including:

- Untreated intra-cranial lesions such as cryptococcal meningitis, or tuberculosis (TB)
- Active pulmonary TB
- Suspected pulmonary Kaposi sarcoma

**9. Do most individual have immediate access to recommended ARVs?**

- Patients enrolled in Medicaid (either managed care or fee for service) can access medications at the time of HIV diagnosis.
- Patients with commercial insurance should be able to obtain ART at time of diagnosis. They may need pharmacy coupons or enrollment in manufacturer-sponsored patient assistance programs, to help with copays or share of cost, especially before their deductible is exhausted.
- NYSDOH’s Uninsured Care Programs (UCPs) have revised the enrollment process to facilitate same-day enrollment. Please contact the New Enrollment Unit, Monday - Friday 8:00am-5:00pm at 1-800-542-2437 or 1-844-682-4058 for information. See page 6 for more information on NYSDOH’s UCPs.
- Manufacturers of medications included in the preferred initial regimens have patient assistant programs that provide free medication or copay assistance to persons newly diagnosed with HIV. These benefits can be immediately activated by a provider through the manufacturer’s website or by telephone.

**10. Who can implement RIA?**

A physician, nurse practitioner, midwife or physician’s assistant can prescribe ART at the time of diagnosis.

**11. What information is needed for RIA?**

The initial visit is a compressed version of the standard initial HIV primary care visit. The clinician takes the patient’s history and performs a focused assessment, with goals of:

- Obtaining enough history to form a decision about whether to start ART and what regimen to use
- Beginning education about HIV, potential benefits of early ART, adherence, and protecting partners
- Engaging the patient to increase their comfort level with the provider and clinic staff, increasing the likelihood of retention in care
- Ensuring required laboratory tests are drawn before treatment is started

**Recommended elements for the initial visit:**

• **History**

<p><b>HIV Risk/Prevention History</b></p> <ul style="list-style-type: none"> <li>• Last negative HIV test</li> <li>• PrEP use</li> <li>• PEP use</li> <li>• Serostatus of partners, if known</li> </ul>	<p><b>Medical History</b></p> <ul style="list-style-type: none"> <li>• Co-morbidities (especially renal/liver problems)</li> <li>• Medications</li> <li>• Drug allergies</li> <li>• Review of systems (include signs of opportunistic infections (OI) or Acute HIV (AHI))</li> </ul>
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• **Baseline Laboratory Tests**

All patients newly diagnosed as living with HIV should have the following laboratory tests performed on the initial visit:

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| <ul style="list-style-type: none"> <li>• HIV 1/2 antigen/antibody assay</li> <li>• HIV quantitative viral load</li> <li>• CD4+ T cell count</li> <li>• HCV antibody</li> <li>• HAV IgG antibody</li> <li>• Urinalysis</li> </ul> | <ul style="list-style-type: none"> <li>• Syphilis serology</li> <li>• HIV-1 genotype (including NRTI, PI)</li> <li>• HBsAg, HBcAb, HBsAb</li> <li>• Metabolic panel (including creatinine &amp; LFTs)</li> <li>• Pregnancy test</li> </ul> |
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*If an individual might qualify for NYS HIV UCP, submit initial lab work to a UCP [participating laboratory](#).*

### ● **Follow up**

Patients started on ART at the first clinic visit need additional education and support in the days and weeks that follow. Models used in NYS clinical settings include phone calls and/or texts in the period immediately following ART initiation and a return clinical visit within the next 7 days.

- Schedule a phone check-in with a social worker, nurse or clinician within the next two days to answer questions and assess for any issues with medication. Because they have recently been diagnosed with HIV and started on ART with little or no advance preparation, they will need additional HIV-related education, information regarding the importance of medication adherence, counseling about preventing HIV transmission, and encouragement about living healthy lives with HIV.
- The first follow-up visit should include medical, nursing, social work, adherence counseling, and partner services information. Review baseline laboratory results including genotype resistance testing. Adjust medications if necessary. Complete a NYSDOH Patient Reporting Form.

### **12. What support and ongoing assistance are required for patients on immediate treatment?**

Newly diagnosed patients treated under the RIA protocol need support from pharmacists, mental health professionals, substance abuse counselors, and social workers. Regional HIV service organizations are located across NYS and provide vital navigation and support services to individuals who are newly aware that they are living with HIV. Knowledgeable staff can assess for potential barriers to adherence such as insurance, medication costs, transportation, and housing, and link patients to available community resources to help maintain medication and appointment adherence. In addition, agency social workers and peers help patients cope with disclosure issues or other stressors related to their diagnosis.

### **13. What if an individual who is newly diagnosed was recently on PEP or PrEP?**

Integrating early treatment in patients who have a reactive HIV test can be clinically straightforward, with minimal risks and substantial benefits. While awaiting results from resistance tests, the DHHS recommends using a regimen consisting of an integrase inhibitor (dolutegravir or bictegravir) + boosted darunavir + TAF/FTC (or TDF/FTC or TDF/3TC) in patients who acquire the infection before or shortly after the use of prophylactic ART.

### **14. Should providers wait for genotype results before prescribing ART?**

For treatment naïve persons, no. The goal of RIA is to remove barriers to ART initiation. The regimens recommended for initial treatment provide a high barrier to resistance while the results of the screening genotype are pending. Therefore, providers should not wait for genotype results before starting ART but should instead modify the regime if indicated by the genotype results.

### **15. Should providers wait for psychosocial stabilization before ART initiation?**

Patients who want to start treatment immediately should have that choice when possible. While patients with untreated mental health, active substance use, immigration issues and/or marginal housing face barriers to successful adherence and linkage, they deserve the highest standard of HIV care, which includes the option of RIA. Despite individual barriers, most patients can achieve viral load suppression taking recommended medication, in conjunction with appropriate counseling and contingency management plans that address immediate issues. Linkage to support services for help with significant issues will improve long term engagement.

### **16. What does RIA mean for the patient?**

The offer of treatment on the day of diagnosis has been shown to improve adherence and retention in care. Immediate treatment is expected care with other medical conditions and RIA reinforces the urgency of treatment, importance of viral load suppression and need for medication adherence.

- Readily available treatment reduces anxiety and uncertainty associated with the extended waiting time for an appointment, baseline evaluations and tests prior to routine treatment.
- Even as patients adjust to their new diagnosis, starting treatment can represent an active, responsible decision to improve health and prevent HIV transmission.
- Taking ART as prescribed helps the patient achieve an undetectable viral load faster and minimizes the risk of sexually transmitting HIV to their partner(s).
- Patients offered treatment at time of diagnosis rate their patient care experience positively.

## 17. Should a patient wait to start ART until a long-term relationship with an HIV provider has been established?

Patients should NOT wait to start ART until a relationship with an HIV provider has been established. Data from New York City, San Francisco and other rapid treatment sites show that this process can take weeks to months, delaying treatment. Rapid initiation protocols allow for the simultaneous initiation of ART and establishment of a patient-provider relationship.

## 18. What treatment regimens are suggested for rapid initiation of ART?

The following regimens are taken from the [NYSDOH Clinical Guidelines "Selecting an Initial ART Regimen"](#)

Table 1: "Preferred Initial ART Regimens for Nonpregnant Adults". Each regimen consists of two nucleoside reverse transcriptase inhibitors (NRTIs) in combination with a third active ARV drug. Each regimen uses once daily dosing which is intended to facilitate adherence, and all are appropriate for immediate initiation in non-pregnant individuals while laboratory results are pending. The guideline includes other equally efficacious HIV regimens.

<b>Suggested Initial ART Regimens for RIA in Nonpregnant* Adults</b>	
<i>(current as of May 2019)</i>	
Regimen	Comments
<b>Tenofovir alafenamide/emtricitabine/bictegravir (TAF 25 mg/FTC/BIC; Biktarvy)</b>	<ul style="list-style-type: none"> <li>• Initiate <i>only</i> in patients with CrCl <math>\geq</math>30 mL/min.</li> <li>• Contains 25 mg of TAF, unboosted.</li> <li>• 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.</li> </ul>
<b>Tenofovir alafenamide/emtricitabine and dolutegravir (TAF 25 mg/FTC and DTG; Descovy and Tivicay)</b>	<ul style="list-style-type: none"> <li>• Initiate <i>only</i> in patients with CrCl <math>\geq</math>30 mL/min.</li> <li>• Documented DTG resistance after initiation in treatment-naive patients is rare.</li> <li>• Contains 25 mg of TAF, unboosted.</li> <li>• 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.</li> </ul>
<b>Tenofovir alafenamide/emtricitabine and raltegravir (TAF 25 mg/FTC and RAL HD; Descovy and Isentress HD)</b>	<ul style="list-style-type: none"> <li>• Initiate <i>only</i> in patients with CrCl <math>\geq</math>30 mL/min.</li> <li>• To date, no clinical trials have been conducted with TAF and RAL; data are based on bioequivalence pharmacokinetic studies.</li> <li>• Contains 25 mg of TAF, unboosted.</li> <li>• Administer as TAF/FTC once daily and RAL HD 1200 mg once daily, dosed as two 600 mg HD tablets.</li> <li>• Magnesium- or aluminum-containing antacids are contraindicated; co-administration of calcium-containing antacids is not recommended with RAL HD.</li> </ul>
<p>* ART Regimens for individuals of childbearing potential: Refer to the DHHS guideline: <a href="#">Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States.</a></p>	
<p>For dose adjustments based on renal or hepatic function refer to the table: <a href="#">ARV Dose Adjustments for Renal and Hepatic Impairment.</a></p>	

Clinical guidelines are frequently updated; refer to [Selecting an Initial ART Regimen](#) for the most current recommendations.

## 19. What regimens are NOT recommended for immediate ART?

Abacavir-containing regimens are not recommended for immediate ART, since ART is begun while HLAB-5701 testing is pending. Tenofovir plus emtricitabine is the preferred nucleoside backbone. Tenofovir is unlikely to cause renal impairment in the several days before HLAB5701 results are available. Tenofovir + emtricitabine can be replaced with abacavir + lamivudine once the patient is confirmed HLAB-5701-negative.

## **Information on NYS Uninsured Care Programs**

The Uninsured Care Programs provide access to free health care (drugs, outpatient primary care, home care, insurance premium payments, and pre-exposure prophylaxis to prevent HIV infection) for NYS residents who are uninsured or underinsured. Financial eligibility is based on 500% of the Federal Poverty Level (FPL). Acknowledging the critical need for rapid access to ARV therapy, the UCP has revised the enrollment process to facilitate same-day enrollment. Please contact the New Enrollment Unit, Monday - Friday 8:00am-5:00pm at 1-800-542-2437 or 1-844-682-4058 for information.

A provider must be enrolled as an ADAP Plus provider on the day that services are provided in order to receive reimbursement. Providers who are active with the NYS Medicaid Program are eligible to enroll in the UCP. To become an enrolled provider, contact the UCP Provider Relations Department at 1-518-459-1641 or email [damarys.feliciano@health.ny.gov](mailto:damarys.feliciano@health.ny.gov). Eligible providers will be activated the date the application is received.

## **Clinical Guidance**

Questions frequently arise in the evaluation and management of persons with new HIV diagnoses. These include uncertainties about interpretation of discordant HIV test results, risk of transmitted or acquired drug resistance, and decisions about which ART regimens to start. The following resources are available:

- **[Clinical Education Initiative](#)**

**(CEI) LINE: Call 866-637-2342** to speak to an experienced HIV clinician regarding HIV.

- **New York State Department of Health AIDS Institute**

- **[Clinical Guideline for Selecting an Initial ART Regimen](#)**

Provides evidence-based guidance on:

- Available ART Regimens
- General Principles in Choosing an Initial ART Regimen
- General Considerations with Initial ART Regimens
- Specific Factors to Consider and Discuss with Patients
- Special Considerations for Comorbid Conditions
- Pre-ART-Initiation Laboratory Testing
- ART Dose Adjustments for Renal and Hepatic Impairment

- **US Department of Health and Human Services:**

- **[Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV](#)**