Immediate Initiation of HIV Treatment: Guidance for Medical Providers
Updated January 2021

Initiating antiretroviral therapy (ART) on the day of diagnosis or first clinic visit is now the recommended standard of HIV care in New York.

This approach aligns with guidelines from the New York State (NYS) Clinical Guidelines Program, International Antiviral Society-USA, and World Health Organization that recommend initiating HIV treatment as soon as the day of diagnosis. The U.S. Department of Health and Human Services (DHHS) recommends starting treatment promptly after diagnosis.

The benefits of immediate ART

Evidence from a range of randomized clinical trials establishes that initiating ART on the day of diagnosis increases the proportion of patients who were virally suppressed and retained in care after 12 months. Immediate treatment allows patients to engage in HIV care without delay and can empower them to disclose their status to partners, friends and family.

Clinical studies have shown that early treatment of HIV:

- Promptly suppresses a patient's viral load, which decreases inflammation and immune activation that may contribute to end-organ damage
- Prevents the selection of drug-resistance mutations
- Prevents HIV transmission to others

Indications and contraindications

Offer ART immediately to:

- Patients newly diagnosed with HIV based on either a lab test or a point-of-care test (including before diagnosis is confirmed)
- Patients previously diagnosed with HIV who never received ART or previously took HIV treatment medicines regularly

Do not provide immediate HIV treatment to:

- Patients for whom immediate ART might be medically dangerous (for example, with clinical signs or symptoms of cryptococcal meningitis or tubercular meningitis) due to the risk of immune reconstitution inflammatory syndrome (IRIS)
- Patients who are likely to have multiple mutations to antiretroviral medicines (for example, with prior HIV treatment experience and known or suspected resistance), as results of resistance testing may influence the choice of an ART regimen

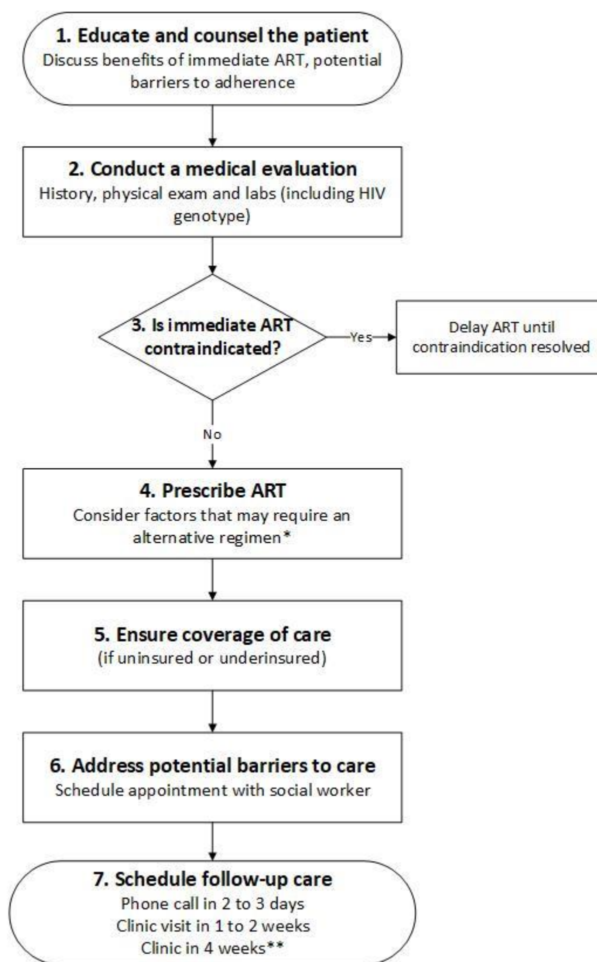
Prescribing before lab results

To expand immediate access to HIV treatment, providers should *routinely* initiate ART at the first HIV-related visit while collecting blood for a genotype to test for drug resistance, a test of kidney function, a confirmatory HIV test (if needed) and other lab work.

Clinicians may be uncomfortable prescribing a regimen before lab results establish whether the patient has confirmed HIV infection, renal insufficiency or medication-resistant virus (see the "Challenging scenarios" section in this document). Clinical experience with immediate ART suggests that providers seldom have to stop or alter the initial regimen.

Once genotype results are available, clinicians may *occasionally* need to modify the initial ART regimen if results indicate the presence of medication-resistant virus. Standard initial regimens recommended by DHHS and NYS provide a high barrier to the development of resistance while genotype results are being processed.

Clinical steps in same-day initiation of ART



*Liver or kidney disease or recent inconsistent PrEP or PEP use
**Quarterly thereafter

Clinical steps in same-day initiation of ART

1. Educate and counsel patients on HIV and immediate ART

It is ultimately the patient's decision whether they are ready to start HIV treatment. Providers can inform this decision by describing the goal and benefits of immediate ART.

Counsel patients that:
- The **goal of treatment** is to reduce the HIV in your body to an undetectable level – this limits the damage that the virus can cause to your body and immune system.
- Medicines to treat HIV are **safe and suppress the HIV** in your body.
- Starting HIV treatment **today** – and taking your medicines as prescribed – will help **get your HIV to undetectable as quickly as possible**.
- If you keep the HIV in your body at an undetectable level, you will not pass the virus through sex. This is known as undetectable equals untransmittable, or U = U.

In addition, discuss with patients:
- How lab results might require a change in their ART regimen
- How they should reach out to you if side effects or other issues make it difficult for them to take their medicines every day
- A schedule for follow-up visits and the role of viral-load monitoring

2. Conduct a medical evaluation

Following DHHS and NYS clinical guidelines on the diagnosis and management of HIV, conduct:
- A standard HIV and general medical history
- A physical exam
- Baseline laboratory tests (including genotype testing to determine if the patient's virus is resistant to HIV medicines)

HIV-Related History	Physical Exam and Medical History
• Last negative HIV test • Use of PrEP (pre-exposure prophylaxis) (past, current) • Use of PEP (post-exposure prophylaxis) (past, current) • HIV status of sexual partners, if known • Recent sexually transmitted infections	• Review of systems (particularly for the presence of opportunistic infections or symptoms of acute HIV infection) • Comorbidities (especially kidney or liver disorders) • Drug allergies • Medications

Baseline Laboratory Tests	
• Confirmatory HIV testing with antibody or antigen/antibody testing (if not already conducted) • HIV genotype • HIV viral load • CD4+ cell count (T cell count) • HLA-B*5701 polymorphism testing • 3-site (urine, pharyngeal, rectal) gonorrhea and chlamydia nucleic acid amplification test (NAAT) • Syphilis screening • HAV IgG antibody • Hepatitis B serology (HBsAg, HBsAb, and HBcAb) • Hepatitis C antibody (with reflex to RNA)	• Comprehensive metabolic panel • Fasting blood glucose (if feasible) or hemoglobin A1C • Fasting lipid profile (if feasible) • Complete blood count (CBC) with differential • Urinalysis • Pregnancy test • Also consider a blood test for tuberculosis, Toxoplasma IgG antibody and G6PD testing • Additional tests indicated by the patient's medical history

3. Contraindications to immediate ART

If the patient has a prior history of irregularly taking ART, delay prescribing an initial regimen until receipt of a genotype.

If the patient has signs or symptoms of severe opportunistic infections, delay ART until it is safe to initiate (see guidance on acute opportunistic infections and ART initiation).

4. Prescribe an initial regimen

Providers are encouraged to select a regimen containing potent nucleoside reverse transcriptase inhibitors (NRTIs) and an integrase inhibitor, **preferably in a single pill that can be taken once a day.**

- DHHS and NYS provide complete lists of preferred and alternative regimens for immediate ART.

Regimens for immediate ART should not contain abacavir, an NRTI.

- HLA-B*5701 testing is required before prescribing abacavir due to concern for a life-threatening hypersensitivity reaction.
- If the patient is confirmed as HLA-B*5701-negative, tenofovir + emtricitabine (the preferred NRTI backbone) can be replaced with abacavir + lamivudine, if indicated.

Consider factors that may require an alternative regimen but may not be apparent at the baseline visit. These include:

- Severe liver or kidney disease and the potential for drug-drug interactions
- Recent inconsistent use of PrEP or PEP

In these situations, the benefits of immediate ART outweigh the risks of the patient taking a standard ART regimen until the regimen can be adjusted based on lab results.

5. Ensure coverage of care

HIV treatment is available to all New Yorkers. Assess patients for insurance coverage and connect them to any needed financial support for immediate ART.

For uninsured and underinsured patients

- The NYS Uninsured Care Programs provide access to free health care and medicines to New Yorkers with HIV. An expedited application process allows same-day enrollment into the NYS AIDS Drug Assistance Program (ADAP) and ADAP-Plus, which cover services and medicines provided by ADAP-enrolled clinicians and pharmacies up to 30 days *prior* to enrollment.
- The NYS RapidTx program supports clinics that regularly diagnose HIV to provide a one-month supply of medicines to uninsured or underinsured patients on the day of diagnosis. Check with your administrator to see if your clinic is part of RapidTx.
- Patients with lower incomes can also apply for Medicaid or a NYS of Health Essential Plan.

For insured patients

- Patients enrolled in fee-for-service or managed-care Medicaid can access immediate ART.
- Patients with commercial health insurance should receive coverage for HIV treatment but may also benefit from pharmacy coupons or pharma-sponsored patient assistance programs that cover copays and cost-sharing.

Pharma support for patients

- Patient assistance programs and pharmacy coupons can cover costs related to initial medications.

6. Address potential barriers to care

On the day of ART initiation, clinic staff should assess patients for social and psychological stability, including housing status, mental health and substance use.

Encourage patients to contact the clinic right away if they struggle to take HIV medicines every day or if they want to stop treatment. New York City (NYC) HIV Care Coordination programs provide support to Ryan White Care Coordination-eligible patients in participating clinics who struggle to take their HIV medicines or stay in care.

7. Schedule follow-up care

Follow up with the patient to assure adherence to treatment, repeat lab work, possibly adjust the regimen, and address any complications to ART, through:

- A check-in in two to three days, by the patient's preferred method of contact
- A clinical visit in one to two weeks, after receipt of the genotype
- A clinical visit at four weeks, to obtain a quantitative viral load

- Clinical visits approximately quarterly thereafter, following guidelines

Clinical experience with immediate ART

Real-world clinical experience suggests that providers seldom have to stop or alter the initial ART regimen. In 2017, NYC's Sexual Health Clinics began routinely offering ART on the day of HIV diagnosis. Of 130 patients who were provided immediate ART:

- 10 had a false-positive test result (and were told to discontinue ART)
- None had a GFR < 50mL/min (indicating moderate renal insufficiency)
- Only two had virus resistance to one of the drugs in the standard initial regimen (tenofovir alafenamide/emtricitabine/dolutegravir)
- Only one patient required a change in their initial treatment regimen

Challenging scenarios

If a patient receives a positive result from a rapid point-of-care HIV test

- It is appropriate to initiate ART based on a positive point-of-care HIV test. Most positive test results will be true positives.
- If subsequent lab testing determines that a positive point-of-care test was a false positive, ART can be promptly discontinued.
- Discuss with the patient the possibility that a point-of-care test could be a false positive, so they are not surprised if a lab test does not confirm HIV infection.

If the patient is reluctant to start HIV treatment

- Do not insist that the patient initiate ART immediately.
- Work with social work and navigation staff to explore any barriers to care and provide support.
- Schedule a follow-up visit to see if they are ready to start treatment and stay in contact.

If the patient has social or psychological barriers to care

- Help them address any issues with mental health, substance use or unstable housing. These barriers **should not** delay the offer of immediate treatment.

If the patient may become pregnant

- Neural tube defects have previously been described in babies born to people taking dolutegravir during conception or pregnancy.
- In response to recent clinical findings on dolutegravir's safety, the World Health Organization has restored recommending the drug as part of a first-line regimen for all adults newly diagnosed with HIV, including patients who may become pregnant.

If the patient is hospitalized

- Immediate treatment is indicated for most inpatients, as long as they are not hospitalized for cryptococcal meningitis or other serious intracranial infections.
- Inpatient initiation can help eliminate administrative or structural barriers to starting certain patients on ART.

Preparing your clinic or testing program for immediate ART

- **Link to HIV care clinics:** Non-clinical testing programs (and clinics that do not provide HIV care) can establish linkages to nearby clinics that provide same-day or next-day care appointments to people newly diagnosed with HIV.
- **Ensure pharmacy access:** Clinics can use on-site pharmacies and clinic and patient assistance programs to provide medication starter packs that allow patients to begin taking ART at the initial visit, even before insurance coverage is established.
    - Clinics without on-site pharmacies can establish agreements with nearby pharmacies to quickly get HIV medicines to patients. Request that pharmacies agree to immediately fill prescriptions for uninsured patients who have completed an ADAP application and deliver HIV medicines to the clinic, so patients can take their first dose at the initial visit.

Resources

- For clinical HIV care support, contact the NYS Clinical Education Initiative line at 866-637-2342.

More Information

- Immediate Initiation of HIV Treatment
- Letter to Medical Providers on Immediate ART
- NYC Health Map – Same-Day or Next-Day HIV Care Providers (under HIV and HIV Treatment)
- HIV Information for Providers
- NYC HIV Home Page