HENNEPIN COUNTY
MINNESOTA

Rapid Start: Minimum Standards and Implementation Considerations

Minneapolis – St. Paul Transitional Grant Area (TGA)

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Hennepin County Public Health

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Introduction & Background

Vision Statement

Rapid Start is the standard of care within the Minneapolis-St. Paul TGA. Everybody recently diagnosed with HIV or out of care has the same opportunity to receive Rapid Start services. Rapid Start is defined as the initiation of antiretroviral treatment (ART) for HIV on the same day or within 7 days of HIV diagnosis or re-engagement in care. Rapid Start services in the TGA are easily & equitably accessible, trauma-informed, and culturally competent.

Definitions

Rapid ART is the identification, linkage and provision of outpatient HIV care and treatment for newly diagnosed individuals and individuals not engaged in care **on the same day or within seven days** of initial HIV diagnosis or re-engagement in care. Outpatient HIV care and treatment includes diagnostic and therapeutic services provided directly to a client by a licensed healthcare provider in an outpatient medical setting.

Rationale

Starting ART immediately after HIV diagnosis is recommended by U.S. federal guidelines. Immediate ART (same-day ART, or iART) and Rapid ART can result in earlier HIV viral suppression, improved retention in care, and reduced HIV transmission. Timely treatment reduces community spread and minimizes progression of HIV in those recently diagnosed. Those who are undiagnosed or untreated are much more likely to transmit HIV to others. Rapid ART initiation may improve the equity and accessibility of ART for people who may otherwise be lost to follow-up during ART preparation sessions. Immediate treatment allows clients to engage in HIV care without delay and can empower them to disclose their status to partners, friends and family.[1]

Scope

This Minimum Standard document is intended to guide HIV treatment and testing providers in the Minnesota-St. Paul Transitional Grant Area (TGA) towards best practices in implementing Rapid Start. Providers can use this resource to establish written policies and practices for Rapid Start, such as policies required to be established for Part A Outpatient/Ambulatory Health Services as specified in the Part A Service Standards approved by the Minnesota HIV Council in 2024.

Clinical Implementation

Persons appropriate for Rapid Start

Rapid Start IS appropriate for:	Rapid Start is NOT appropriate for:
• Anyone with a new HIV diagnosis* unless there is a clear contraindication • Persons with possible acute HIV • People with HIV who are re-engaging in care: Restart ART immediately if possible and if drug resistance can be predicated and accounted for in the new ART regimen	• Patients for whom immediate ART might be medically dangerous (e.g., untreated central nervous system opportunistic infections such as cryptococcal meningitis • Patients likely to have multiple ARV mutations (e.g., treatment experienced with known or suspected resistance) for whom it would be difficult to design an ART regimen without current resistance test results

This includes nearly all individuals with a confirmed new diagnosis of HIV (i.e., HIV Ag/Ab, and/or HIV RNA viral load) **and persons with positive results of rapid HIV antibody tests, before confirmatory test results are available, if the concern for HIV infection is high (after counseling, immediate ART can be offered with the understanding that if confirmatory tests are negative, the patient would stop ART)*

HIV Diagnosis & Testing Protocols for Rapid Start

Typically, patients start Rapid ART after a confirmed positive HIV test.

- A confirmed positive test will depend on the testing algorithm used:
- reactive lab-based 4th generation antigen/antibody + reactive antibody differentiation
- reactive antibody + reactive confirmatory antibody
- 2 different reactive single-use rapid antibody tests

Occasionally, a patient will present with:

- Positive HIV RNA (quantitative or qualitative viral load) + non-reactive antibody
    - Indicates acute HIV infection. Immediate ART may be offered before confirmatory testing results are available.
- Reactive lab-based 4th generation antigen/antibody + non-reactive differentiation antibody
    - Indicates either acute HIV infection or false positive Ag/Ab test. If the patient is at high risk for HIV infection, they may be referred for Rapid ART initiation before the results of the "tiebreaker" HIV RNA is available to clarify the diagnosis.

The decision to start ART should be made with shared decision-making and the patient's understanding that they may take ART for several days in the setting of a false positive initial HIV test. If HIV negative, transition to PrEP can be considered.

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), hepatitis B serologies, and other appropriate lab work.

Clinicians may be uncomfortable prescribing a regimen before lab results confirm an 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.

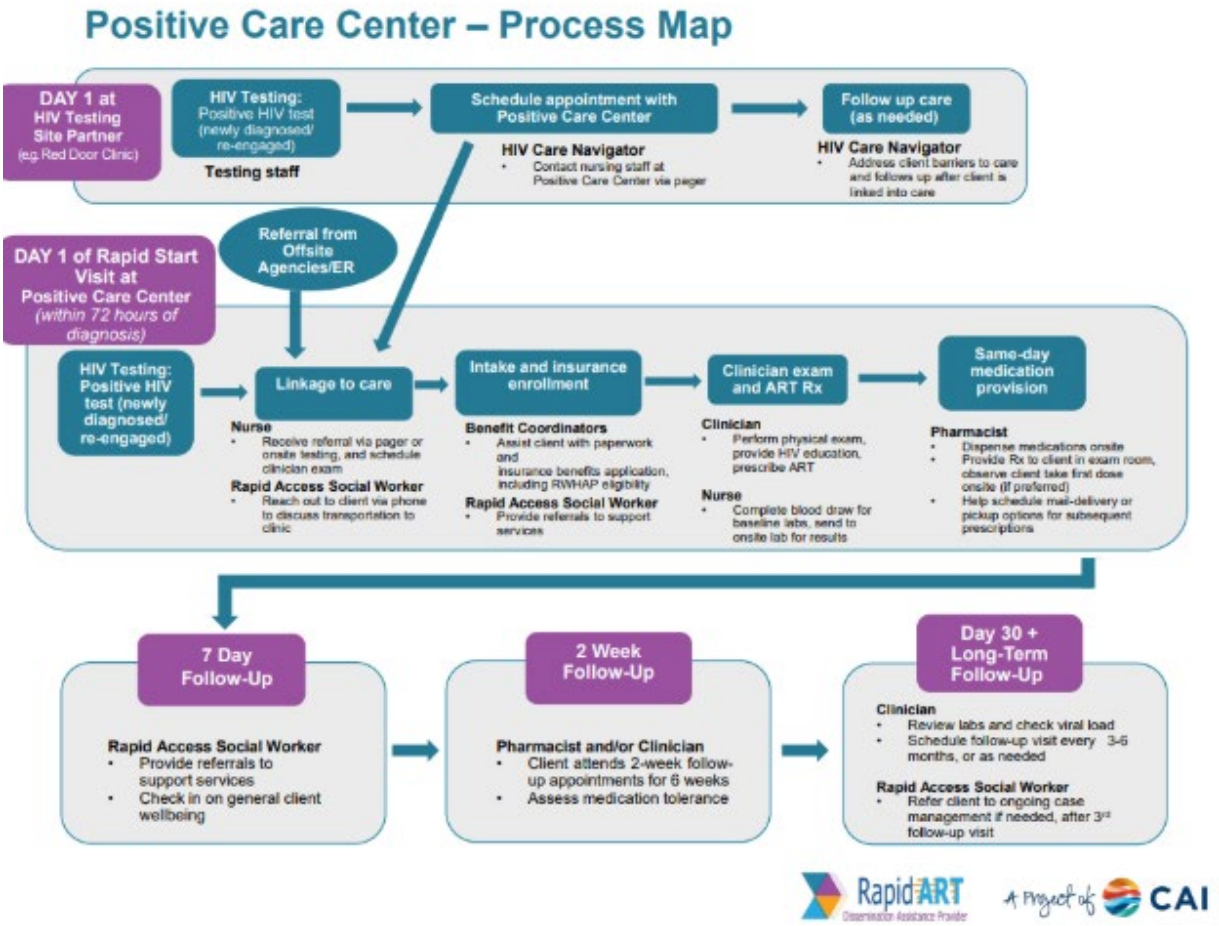
Once HIV genotype results are available, clinicians may need to modify the initial ART regimen if results indicate the presence of medication-resistant virus, although this is rare. Standard initial regimens recommended by the CDC provide a high barrier to the development of resistance while genotype results are being processed.

Seek expert advice in cases with discordant test results or complicated clinical scenarios. The initial rapid ART regimen selected should have activity against hepatitis B if the hepatitis B viral status is unknown (eg. BIC/TAF/FTC or tenofovir-containing regimen), and hepatitis B serologies are important to avoid the risk of a potential hepatitis B flare in the future if the patient is living with chronic HBV and HIV and decides to change ART regimens for any reason.

Rapid Start Workflow & Activities

A basic Rapid Start process involves testing, linkage to Rapid Start care, intake & insurance enrollment, clinician exam, ART prescription, medication dispensing/provision, and referral to follow-up and supportive services, though not necessarily in this order.

An example process map based on the Positive Care Center is available below:



Rapid Start processes may vary based on staffing, clinic flows, and linkage resources available. A client's Rapid Start journey may involve multiple provider locations and referrals, such as in situations where clients are newly diagnosed by a testing provider and referred to a different provider for Rapid Start and broader care services.

Beyond establishing a clinical workflow, other key implementation activities for Rapid Start programs may include:

- **Develop and implement internal Rapid Start policy**: Develop and implement Rapid ART policy guidelines, protocols, best-practices, process map for linking client to ART within 7 days of new dx and achieving viral load suppression.
- Appointing a designated **Rapid Linkage Coordinator/Champion**.

- **Establish a designated Rapid ART Program phone line**, with availability after business hours for referrals. Voicemails will be returned within one business day. If the designated person for the phone line is off work, alternate staff must be assigned.
- **Specify the designated staff** for receiving phone calls, make appointments, and provide necessary information during the phone call with clients.
- **Utilize case managers/navigators** (particularly those who reflect the community they serve) and their role in the interdisciplinary team to support rapid linkage to care and help clients navigate the HIV system to support future retention in care.
- **Health education** and wellness engagement of the clients will be provided during the first Rapid ART visit.
- **Mental health services** and appropriate referrals are made available to clients in need during this initial visit.
- **Addiction medicine Services** and appropriate referrals are made available to clients in need during this initial visit.

Care Team & Staffing

Key staff roles in a Rapid Start program may include:

- Clinician
- Rapid Start navigator
- HIV case manager
- Benefits/insurance navigator
- Medical personnel skilled in phlebotomy for bloodwork
- Pharmacist

Many of these roles can be filled/supported by a variety of staff positions including DIS, medical assistants (MA), LPNs (Licensed Practical Nurses), case managers, Licensed Alcohol and Drug Counselors (LADCs), social workers, outreach staff, linkage to care coordinators, non-medical case managers, etc.

Prescribing & Clinical Services

Any clinician* who is able to prescribe medications can be a Rapid Start clinical provider – while follow-up care with an HIV specialist is important, neither Providers with specialty training in HIV nor infectious disease clinicians are a requisite part of implementing Rapid Start programs if these providers have ready access to specialists in HIV for complex cases or questions. In Minnesota, advance practice registered nurses (APRNs) - including nurse practitioners (NPs) – and physician assistants (PA)** can independently prescribe medications and RNs and LPNs can prescribe medications under standing orders from a physician.

*Minnesota licensed pharmacists are authorized to prescribe and administer PrEP and nPEP for HIV prevention but are **not** authorized to prescribe ART for treatment of HIV.

**PA scopes of practice may vary dependent on individual collaborative and/or practice agreements.

A Closer Look: Clinical Steps in Same-Day Initiation of ART (Adapted from NYS Action Guide)

1. Educate and counsel patients on HIV and Rapid ART

Ultimately, it is 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. Any provider prescribing ART will want to be familiar with side effects of the most common ART drugs prescribed and some background knowledge of HIV to help educate the patient (see below).

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 but do not cure it.
- Suppressing the HIV virus allows the immune system (T cells, called CD4 cells) to rebuild and to continue to protect the body from infection and cancer.
- 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 cannot pass the virus through sex. This is known as undetectable equals untransmittable, or U = U.

In addition, discuss with patients:

- Common side effects of the medication
- That lab results or side effects could require a change in their ART regimen in rare circumstances.
- That they should reach out to the clinic if they develop any 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 CD4 and viral-load monitoring and surveillance labs to monitor for liver or kidney injury related to the medications.

2. Conduct a Medical Evaluation

Following DHHS and Minneapolis-St. Paul TGA clinical guidelines on the diagnosis and management of HIV, conduct:

- A standard HIV and general medical history
- A physical exam
- Baseline laboratory tests (including HIV genotype testing to determine if the patient's virus is resistant to HIV medicines); this baseline genotype does not typically include screening for integrase inhibitor resistance **unless** the patient has been on injectable cabotegravir for PrEP in which case the provider should order HIV integrase inhibitor resistance testing at baseline. These patients should be referred to an experienced HIV provider to manage if integrase inhibitor resistance is present.

*(See "History and Labs Cheat Sheet" in appendix for more information)

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 (eg. Cryptococcal meningitis, active tuberculosis, CMV retinitis), consult with an ID/HIV provider and delay ART until a specialist indicates it is safe to initiate (see guidance on acute opportunistic infections and ART initiation). The risk of IRIS (immune reconstitution inflammatory syndrome) is high in these conditions, and timing of therapy needs to be carefully considered before ART initiation in these select patients with AIDS on presentation.

4. Prescribe an Initial Regimen

See "Same-Day ART Access" below for more information on accessing starter packs

Clinicians should prescribe ART immediately for clients without contraindications following initial HIV diagnosis. While awaiting laboratory-confirmed test results, prescribe and dispense* 7- to 14-day starter prescriptions of ART:

- Prescribe & dispense medications through onsite pharmacy if applicable
- Prescribe starter pack & fill at partnering pharmacy or pharmacy of client's choice (see *pharmacy partnerships* below)
- Dispense pharmaceutical sample pack, usually 7 or 14 days, onsite

After HIV diagnosis is confirmed, dispense a Rapid ART prescription with a 30-day prescription or fill additional starter packs, until eligibility for other program(s) is determined.

Option A: Medication Available on-site (samples or starter packs)

- Once an ART regimen has been selected, the health team dispenses a 7-day (or other amount) supply of medications (having recorded the order in the medical record). The goal is to provide sufficient ART until the patient's ADAP or insurance is active and covers a standard monthly supply. In situations where this period is anticipated to be longer than 7, additional pills may be dispensed.
- The patient is encouraged to take the first dose of ART during the initial Rapid Start visit.
- In the patient's medical record, the clinician creates an order for a standard 30-day supply of the same ART regimen and transmits it to the appropriate pharmacy.
- The clinician or designated staff CALLS the pharmacy to alert them to the incoming ART prescription, and that it is to be filled as soon as possible.

Option B: Medication NOT Available on site

- Once an ART regimen has been selected and emergency/presumptive ADAP, Medical Assistance (MA), or MinnesotaCare is initiated (see step 5 and "Eligibility" for more information), or if the patient already has insurance, the clinician writes a 30-day prescription and sends it to the appropriate pharmacy. If there are any delays to coverage activation, the use of pharmaceutical company medication assistance coupons is highly recommended, to ensure same-day initiation (see "Eligibility" for resources)
- The clinician or designated staff CALLS the pharmacy to alert them to the incoming ART prescription, and that it is to be filled as soon as possible (this will also alert the clinician to any stock-outs or other problems at the pharmacy).

Regimens

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.
- The initial rapid ART regimen must include hepatitis B coverage (a tenofovir containing regimen) unless the hepatitis B status is already known, to prevent HBV flare.

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

- Documented negative testing for HLA-B*5701 is required before prescribing abacavir due to concern for a life-threatening hypersensitivity reaction. This test can take 1-2 weeks to return, so abacavir is not part of rapid ART regimens, nor is it part of any 1st line regimens for HIV management due to cardiovascular risk.
- 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 may outweigh the risks of the patient taking a standard ART regimen until the regimen can be adjusted based on lab results.

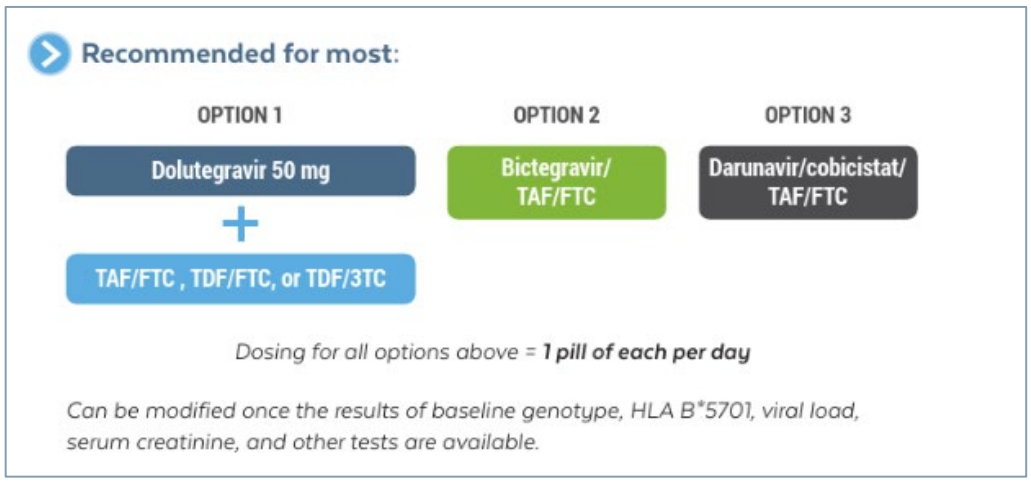


Fig 1. Sample regimens from the San Francisco Department of Public Health's "Detailing Aid for Rapid Initiation of HIV Anti-Retroviral Therapy" (2025).

5. Ensure Coverage of Care

Assess patients for insurance coverage and connect them to any needed financial support for Rapid ART:

For uninsured and underinsured patients

- Program HH (the Ryan White HIV/AIDS Program in Minnesota) provide access to free medicines to Minnesotans with HIV through the ADAP program, with additional coverage for medical visits and other outpatient ambulatory health services for residents of the Minnesota-St. Paul region eligible for Part A of Program HH/RWHAP. Providers (i.e., benefits navigators, non-medical case managers, etc) should begin the eligibility application on the same day as the initial Rapid Start visit and provide either 1) an ART starter prescription to retroactively bill to Program HH once the application is approved, or 2) a sample medication pack from pharmaceutical manufacturers or purchased by the provider through funds such as 340B rebates. *See "Eligibility" below for more information on ensuring coverage of care for Rapid Start services.*
- Medical Assistance (MA), Minnesota's Medicaid program for people with low income, and MinnesotaCare, a program for people with low income who do not qualify for MA, can cover HIV medical care and other supportive services. Benefits navigators should simultaneously support client applications for MA/MinnesotaCare and Program HH to streamline collection of documentation and ensure Program HH is used as payor of last resort.

For insured patients

- Patients enrolled in fee-for-service or managed-care Medicaid can access immediate ART.
- Patients with commercial health insurance such as plans through MNSure, the state's health insurance exchange, 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, though same-day ART initiation can be more difficult in these scenarios given paperwork requirements.

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. Staff such as case managers and client navigators should refer clients to social services providers as indicated and schedule warm handoffs as possible.

7. Schedule or refer to 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. Check in with the patient by phone in 2-3 days, and in the clinic (or telehealth) in 1-4 weeks. If referring a client to ongoing care at a different provider, conduct a warm handoff as possible and follow up with the new provider to confirm that the patient has received follow-up care.

Same-Day ART Access: Pharmacy partnerships & pharmaceutical samples

Providers can facilitate same-day access to ART using sample packs and/or by dispensing starter medications through onsite or partner pharmacies. Providers often use a combination of approaches based on client insurance status or preference.

Tips for pharmacy partnerships:

- Strengthen relationships with multiple external pharmacies with considerations for client convenience and consider establishing MOUs or collaborative practice agreements (CPA) to ensure priority filling for Rapid Start prescriptions and ensure starter packs are dispensed for clients with pending eligibility applications for RWHAP, where applicable (see "Eligibility" section for more information)
- Send electronic prescriptions to pharmacies
- Send electronic flags to the pharmacy's system to indicate the client is a Rapid Start client and should be prioritized
- Utilize electronic flags in the EHR for pharmacies to indicate whether the client filled the prescription or not

Starter packs and pharmaceutical samples

Many providers offer a first fill of medication through an ART starter pack or sample. These are 7 to 30 days of medications which are often given to providers by pharmaceutical companies. This allows enough time for clients to become approved for health care coverage, including Medicaid and Ryan White HIV/AIDS Program ADAP, after the initial dispense.

Many clinics work with pharmaceutical manufacturers to access free sample packs. This usually involves coordinating with a regional account manager to arrange delivery of samples directly to providers for sign-off and storage (for example, Viiv generally distributes 8 samples per month per providing clinician). Clinicians are responsible for tracking and reporting utilization of sample packs in coordination with the manufacturer and clinic/institutional policy for accepting, storing, and dispensing medications.

Providers utilizing donated/pre-purchased ART sample packs should consult their legal team to understand necessary conditions for medication storage, dispensing, and reporting. A template policy for accepting and using donated sample packs is available in the Appendix.

To connect to pharmaceutical manufacturers to arrange sample pack donations, contact:

Gilead (Biktarvy): Julie Miller, Julie.Miller@gilead.com

ViiV (Dovato): Christine Lichtensteiger, christine.a.lichtensteiger@viivhealthcare.com

If your practice is unable to accept or store donated sample packs but is interested in accessing pharmaceutical samples in urgent situations, contact Red Door (reddoor@hennepin.us) to discuss a referral. Clinics may also purchase medication sample packs using funding such as non-ADAP 340B rebate funding.

Eligibility for Coverage of Rapid Start Services

It is crucial that Rapid Start providers support clients in securing coverage for Rapid Start services. For clients without insurance, this often means applying for RWHAP, Medical Assistance (MA), and/or MinnesotaCare (MNCare) through a benefits navigator, who will work with clients before, during, and following a Rapid Start visit to establish eligibility for these programs.

Providers should supply a starter pack of medications (usually 7 – 14 days) to clients while benefits eligibility is being determined to prevent loss to follow up, a practice known as "presumptive eligibility." In most cases, the pharmacy can retroactively bill those medications once the client is approved for coverage:

"If Program **HH** *approves the person's application, the effective date of Program HH coverage will be the first day of the calendar month Program HH staff received the application. Program HH staff will consider backdating medication coverage on a case-by-case basis if the person submits the request at the same time as the application and there is a compelling reason to do so. Program HH staff will not backdate an application by more than 90 days."*

Sample steps for eligibility for an uninsured client:

- Benefits navigator begins eligibility application for RWHAP, MA/MNCare*
    - If client seems to be eligible based on stated income & residency:
        - Provide starter pack of medication (7 - 14 days)
            - Consider using donated sample packs from pharmaceutical manufacturers
        - Collect verification documentation and prescribe second starter pack if necessary
        - Submit documents for eligibility within 1 month of initial appointment
    - If not presumptively eligible based on stated in come & residency:
        - Use a sample pack from pharmaceutical manufacturers where able for initial appointment
        - Share information and/or help enroll in pharmaceutical Patient Assistance Programs for out-of-pocket help
        - Refer to navigator to support enrollment in Marketplace insurance
        - Refer to clinic with sliding scale

- Once program enrollment has been approved:
    - Retroactively bill** prescription & relevant services (ex. provider visit, lab tests) to the newly enrolled program

*Note: While Program HH / RWHAP /ADAP is the payor of last resort, ADAP will cover the full cost of medications for individuals with pending enrollment in MA, MNCare, Marketplace plans or off-marketplace plans who meet RWHAP eligibility criteria

** Program HH / ADAP and Medicaid allow retroactive eligibility & therefore billing up to 90 days retroactively if the request is included with the coverage application.

Documentation for eligibility applications

Program HH / RWHAP eligibility is based on 4 factors:

1. HIV status (verified by test result documentation, including rapid tests used in rapid-rapid algorithms)
2. Residency (Program HH / ADAP requires MN residency, and Hennepin County Part A services require residency in the 13-county TGA that includes 2 WI counties (Pierce and St Croix))
3. Income (For 2025, must verify income at or below 400% of the FPL)
4. Insurance status (Clients must be uninsured or underinsured as RWHAP is a payor of last resort)

Refer to **Program HH eligibility requirements** for full up-to-date eligibility requirements.

Click here for a list of acceptable verification documents and sources of income.
Click here to access the online application & forms for Ryan White services.

Once eligibility is determined, clients can benefit from applicable supportive services within the Ryan White System of Care. In addition, clients can benefit from a Case Manager supporting them through their care journey.

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.

Tips for providers & benefits navigators:

- Consider establishing a secure web portal for clients to share documentation virtually, if submitting the application/documentation on behalf of a client using the online application
- For clients with smartphones, share instructions for using virtual scanning apps to quickly scan and send documents
- Collate information from multiple programs to reduce number of document requests (ex. complete application for Medicaid and Program HH simultaneously using the same income information, if applicable)

Additional financial resources

- Database: Pharmaceutical Company Patient Assistance Programs and Cost-Sharing Assistance Programs (NASTAD)
- Program HH Eligibility and Application
- MNSure Application
- RWHAP new client & annual certification forms
- Funded MNsure navigators

HIV Navigation & Linkage for Rapid Start

Linkage to care (LTC) – a process to link persons with newly diagnosed HIV to HIV medical care and ART initiation as soon as possible - is a crucial element of Rapid Start services. In the absence of dedicated LTC staff, this role may be filled by those providing HIV services, including patient navigators, social workers, community health workers, case managers, or peer support specialists.

Navigation and LTC Services might include:

- Post-test counseling, education, and support
- Navigating confirmatory testing needs and referrals
- Making referrals and warm hand-offs to initial HIV care services and ancillary services
- Assessing barriers to taking daily medication and engaging in care
- Assessing and addressing medical and medication coverage needs
- Accompanying patients to testing, treatment, and intake appts
- Providing early intervention for missed visits

Successful LTC in a Rapid Start program requires collaboration between clinical and non-clinical staff and may, in some cases, require cooperation between organizations and systems to ensure that individuals newly diagnosed with HIV can fully benefit from Rapid Start.

People with newly diagnosed HIV will require direct referral to LTC staff and a clinical provider to prescribe ART. Programs that have clinical care and clinicians onsite will need to consider provider availability and establish dedicated protocols for rapid ART. Programs that do not reliably have an onsite provider (such as HIV testing sites and community-based outreach programs) will need to identify clinical partners committed to providing rapid ART and develop a referral process with input and memorandums of understanding from all parties. All programs should aim to create a "low threshold" for engagement by limiting the number of handoffs and prioritizing warm handoffs whenever possible, offering flexible appointment times or walk-ins and documented protocols.

Considerations include:

- Determine how patients are referred, what is included in the referral, and who processes referrals
- Create well-defined workflows for clinical and non-clinical roles
- Standardize communication between multidisciplinary teams involved in rapid ART
- Plan for adapting roles and filling gaps in the absence of staff

Tips for Rapid Start service providers:

- Maintain strong relationships with HIV testing sites
- Identify a "go-to" contact and direct communication channels for Rapid Start appointments
- Implement strategies to schedule unpredictable clinic appointments (ex. standing open slots)

**This section was (adapted from Rapid Start Toolkit from Primary Care Development Corp, My Brother's Keeper, San Francisco Community Health Centers, and Denver PTC)*

Monitoring, Evaluation, and Reporting

The below recommended metrics and quality measures for Rapid Start are not required unless specified in your contract. Contact the Hennepin County Ryan White Program Quality Management Coordinator at ryanwhite@hennepin.us for a list of required data and quality measures.

Useful data to collect:

- Demographics
- First positive diagnostic HIV test, or Time Zero Date (TZD): diagnosis date or referral source date. (First date provider is aware of client).
- Last negative HIV test result, if available
- Clinic contact / referral date
- First clinic visit
- First clinic medical provider visit
- First ART prescription or starter pack date (after diagnosis of infection)
- First viral load suppression <200 cells/mm3
- Days to linkage to primary HIV care
- Ongoing HIV primary care medical visit dates

Common Rapid Start Quality Measures

(adapted from San Francisco RAPID Detailing Guide, 2021)

Rapid Start: Initiation of ART within 7 Days	
Description	Percentage persons with HIV newly diagnosed, new to care, and/or out of care who are prescribed HIV antiretroviral therapy within seven days from [time zero]
Numerator	Number of persons in the denominator who are prescribed HIV antiretroviral therapy within seven days from [time zero]
Denominator	Number of persons with HIV newly diagnosed, new to care, and/or out of care in the reporting period
Exclusions	Patients who died, transferred, moved, or were incarcerated in the reporting period

Rapid Start: Median Days to Initiation of ART	
Description	The median number of days from [time zero] to initiation of ART for newly diagnosed, new to care, and/or out of care patients
Numerator	Not applicable
Denominator	Number of persons with HIV newly diagnosed, new to care, and/or out of care who were initiated on ART in the reporting period
Exclusions	Patients who died, transferred, moved, or were incarcerated in the reporting period
Calculation	Determine the number of days from [time zero] to initiation of ART for each patient in the denominator Sort the number of days in ascending order Determine the middle value

Rapid Start: Linkage to HIV Medical Care within 7 days	
Definition	Percentage of persons with HIV newly diagnosed, new to care, and/or out of care patients who are linked to HIV medical care within 7 days of [time zero]
Numerator	Number of persons in the denominator who are linked to HIV medical care within 7 days of [time zero]
Denominator	Number of persons with HIV newly diagnosed, new to care, and/or out of care in the reporting period
Exclusions	Patients who died, transferred, moved, or were incarcerated in the reporting period

Rapid Start: Viral Load Suppression	
Definition	Percentage of persons with HIV newly diagnosed, new to care, and/or out of care with a HIV viral load less than 200 copies/ml at last viral load test by 60 days after initiation of ART
Numerator	Number of persons in the denominator who have an HIV viral load less than 200 copies/ml at last viral load test by 60 days after initiation of ART
Denominator	Number of persons with HIV newly diagnosed, new to care, and/or out of care who initiated ART at least 60 days prior to measurement
Exclusions	1. Patients who died, transferred, moved, or were incarcerated in the reporting period

Rapid Start: Retention to Care	
Definition	Percentage of persons with HIV newly diagnosed, new to care, and/or out of care who initiated on ART with at least 1 medical visit in each six-month period at least 90 days apart
Numerator	Number of persons in the denominator who had at least 1 medical visit in each six-month period of the reporting period at least 90 days apart.
Denominator	Number of persons with HIV newly diagnosed, new to care, and/or out of care who initiated ART in the reporting period
Exclusions	1. Patients who died, transferred, moved, or were incarcerated in the reporting period

Definitions

Rapid Start	
Term	Definition
Rapid Start	Initiation of HIV ART within 7 days of [time zero]
Initiation of ART	Starter pack provided or ART prescription written
Linked to Care	A kept medical visit
Date of Diagnosis	Positive rapid HIV screening test, Confirmatory HIV test, and/or HIV Viral Load
Patient Category*	
Term	Definition
Newly Diagnosed	Any person with a new positive HIV rapid, confirmatory, or detectable viral load test result within 12 months
New to Care	Any person diagnosed with HIV greater than 12 months who has not attended a HIV care medical visit
Out of Care	*Any person diagnosed with HIV with previous engagement in HIV care who has no medical visit or laboratory test result for greater than 12 months and has agreed to return to care*

Time Zero		
Category	Notification Type	Time Zero Definition
Newly Diagnosed	Internal HIV Testing	Date of diagnosis
	External Testing and/or Referral	Date referral agency notifies provider or date of self-referral
New to Care	Internal Never Linked and/or External Referral	Date of first contact with site
Out of Care	Internal Out of Care	Date of re-contact with or by site and agreement to return to care
	External Referral	Date referral agency notifies provider of agreement to return to care or date of self-referral

Support for Rapid Start

Positively Hennepin is committed to making Rapid Start the standard of care for all in our community. For questions about implementing Rapid Start at your clinic or testing site, reach out to Hennepin County Public Health at positively@hennepin.us. Ryan White-funded providers with questions about ongoing services can also reach out to ryanwhite@hennepin.us.

Hennepin County & Minnesota HIV Programs:

- Hennepin County Ryan White Program (Part A) - HCPH
- Program HH (Part B and ADAP) – DHS – Application & eligibility information
    - Contact Program HH Customer Care at dhs.programhh@state.mn.us or 651-431-2398
- Minnesota Council for HIV Treatment and Prevention
- Minnesota HIV Prevention and Testing Services (MDH)

TA and Consultation

- MN-TEL HIV Consultation Network
- National HIV Consultation Warmline: 1-800-933-3413, Mon-Fri 6am-2 PM CST
- AIDS Education & Training Centers:
    - Local MATEC (MN/IA) – Regional MATEC (Midwest) – National AETC

Referral Guide for Supportive Services

- North Minneapolis Resources Guide, 2025 | South Minneapolis Resources Guide, 2025
- RWHAP Providers in Hennepin County, 2025
- Twin Cities HIV Clinical Care and Services Guide – MATEC 2024

Rapid Start Toolkits and Guidelines

- National AETC: Rapid ART Clinical One-Pager and Immediate ART Initiation & Restart Guide
- CDC Rapid Start Toolkit (CDC, 2023)
- Compendium of Best Practices for Rapid Start (HRSA, 2022)

Rapid Start Examples and Perspectives

- Rapid Start Service Delivery Models (HRSA) Rapid Start workflows in 9 diverse clinical settings
- Rapid ART Community and Provider Perspective Videos: (HRSA) Hear from clients and providers of Rapid Start services

Additional Tools

- Rapid Start Cost Estimation Tool (HRSA)
- HIV Prevention, Care, and Anti-Stigma Social Media Toolkit (MDH)
- END HIV MN : Minnesota HIV Strategy 2022 Update

References

UCSF RAPID Detailing Guide 2025: https://ucsf.app.box.com/s/p7501vm2z2fm6qxf32ydclxengr97jky

NYS Rapid ART Guidelines: https://www.hivguidelines.org/guideline/hiv-art-rapid/?mycollection=hiv-treatment#tab_0

Las Vegas TGA Rapid Start Manual: https://lasvegastga.com/wp-content/uploads/2023/08/Rapid-stART-Manual-.pdf

NYC iART Guidance for Clinical Providers: https://www.nyc.gov/assets/doh/downloads/pdf/csi/iart-guidance-medical-providers.pdf

NYC iART Expectations and Pledge: https://www.nyc.gov/assets/doh/downloads/pdf/csi/iart-expectations-and-pledge.pdf and Action Kit: https://www.nyc.gov/site/doh/providers/resources/public-health-action-kits-iart.page

Austin EMA Rapid Start Minimum Standards

Compendium of Best Practices (DAP): https://targethiv.org/library/rapid-art-dap/best-practice-compendium

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Appendix

Appendix A. Cheat Sheet: Baseline History and Labs for New HIV Clients

Reproduced from NYC Health's "Immediate Initiation of HIV Treatment: Guidance for Medical Providers"

Cheat Sheet: Baseline History and Labs for New HIV Clients *See MN Service Standards for Outpatient/Ambulatory Health Services for full list*	
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

Appendix B: Challenging scenarios

Reproduced from NYC Health's "Immediate Initiation of HIV Treatment: Guidance for Medical Providers"

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

- 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.

Appendix C: Coding guide for routine HIV testing in health care settings

Adapted from Las Vegas TGA Rapid Start Manual

TEST PRODUCT

CODE	RAPID TEST MODIFIER	DESCRIPTION
86689		Antibody; HTLV or HIV antibody, confirmatory test (e.g, Western Blot)
86701	92	Antibody; HIV-1
86702	92	Antibody; HIV-2
86703	92	Antibody; HIV-1 and HIV-2, single assay
87534		Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique
87535		Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, amplified probe technique
87536		Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, quantification
87390	92	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multiple step method; HIV-1

TEST ADMINISTRATION

CODE	DESCRIPTION
36415	Collection of venous blood by venipuncture

OFFICE SERVICE

CODE	DESCRIPTION
99385	Initial comprehensive preventive medicine service evaluation and management, 18–39 years of age (new patient)
99386	Initial comprehensive preventive medicine service evaluation and management, 40-64 years of age (new patient)
99395	Periodic comprehensive preventive medicine reevaluation and management, 18–39 years of age (established patient)
99396	Periodic comprehensive preventive medicine reevaluation and management, 40-64 years of age (established patient)
99211-99215	HIV counseling for patients with positive test results; office or other outpatient visit for the evaluation and manage- ment of an established patient

MEDICARE HCPCS CODES

TEST PRODUCT	
CODE	**DESCRIPTION**
G0432	Infectious agent antigen detection by enzyme immunoassay (EIA) technique, quali-tative or semi- quantitative, multiple-step method, HIV-1 or HIV-2, screening
G0433	Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening
G0435	Infectious agent antigen detection by rapid antibody test of oral mucosa transu-date, HIV-1 or HIV-2, screening

ICD 10 - CM DIAGNOSIS CODES

SITUATION	CODE	DESCRIPTION
Patient seen as part of a routine medical exam	Z00.00	Routine general medical examination at a health care facility
Patient seen to determine his/her HIV status (can be used in addition to routine medical ex-am)	Z11.59	Special screening for other specified viral diseases
Asymptomatic patient in a known high-risk group for HIV (can be used in addition to rou-tine medical exam)	Z72.89	Other problems related to lifestyle
Counseling provided during the encounter for the test (add additional code if applicable)	Z71.7	HIV counseling
Returning patient informed of his/her HIV nega-tive test results	Z71.7	HIV counseling
Returning patient informed of his/her HIV posi-tive test results AND patient is asymptomatic	Z21	Asymptomatic HIV infection status
Returning patient informed of his/her HIV posi-tive test results, AND patient is symptomatic	B20	HIV disease
HIV counseling provided to patient with positive test results	Z71.7	HIV counseling
Patient seen as part of prenatal medical examination	V73.89	Patient seen as part of a routine prenatal care
Patient seen for first pregnancy	V22.0	Supervision of normal first pregnancy
Patient seen for other-than-first pregnancy (sec-ond, third, etc.)	V22.1	Supervision of other normal pregnancy
Management of high-risk pregnancy	V23.8	Other High-Risk Pregnancy
Management of high-risk pregnancy	V23.9	Supervision of unspecified high-risk pregnancy

Appendix D. Example Policy: Hennepin County Public Health Clinical Services Sample Medication Policy

Purpose:

The clinics of _____ accept and dispense sample medications from pharmaceutical drug representatives to _____ patients in certain circumstances. This policy will ensure patient safety in accepting, storing, distributing, and disposing sample medications.

Policy:

To provide safe and timely dispensing of medications to _____ patients, it may be advantageous for the clinics of _____ to provide patients with sample medications that are provided by pharmaceutical manufacturers. The below Sample Medications Procedure covers how _____ clinics will determine which medications to accept, the steps necessary to ensure proper storage and dispensing of the medications, proper documentation in the medication record, and proper disposal of expired medications.

Procedure:

Determination of Appropriate Medications:

1. Each clinic will have a designated clinical team that will approve any medication being considered to stock in clinic as a sample medication. Approval will be noted in clinical team meeting minutes.
2. Controlled substances will not be considered for sample medications.

Receipt of sample medications from pharmaceutical representatives:

1. Pharmaceutical representatives must make appointments to drop off sample medications. Appointments are for the purpose of dropping off medications, not for education of staff.
2. Sample medications will be inventoried and logged into the sample medication log book by lot number and expiration date at time of medication reception. Log will include: medication name, manufacturer, and amount received. A member of provider staff (Nurse Practitioner or Medical Doctor) will sign off on acceptance of sample medication from pharmaceutical representative.

Inventory & Storage:

1. All sample medications will be stored in a double-locked secure area (e.g. in a locked cabinet, in a locked room).
2. Sample medications will be stored under conditions considered acceptable under manufacturer guidelines.
3. Sample medication will be checked monthly for expiration dates and rotated by expiration date.
4. Expired sample medication will be discarded in accordance with federal, state, and local laws.

Prescribing

1. Sample medications will only be prescribed in these circumstances:
    a) patients without insurance coverage for the medication
    b) instances of time sensitive administration
2. Medications will be ordered in Epic with class: Sample.

Dispensing:

1. Medication samples shall be dispensed in the original manufacturer's packaging.
2. Sample medications will be dispensed to patients by providers or RNs, using Epic and the Sample Medication Log Book for documentation. The following information will be entered into the log book for each medication Lot#/Exp date.
    a) Patient name and DOB or Epic MRN
    b) Quantity dispensed to the patient and quantity remaining
    c) Date sample set up (if applicable) and date dispensed (i.e. given to patient)
    d) Staff initials
3. Sample medication will be labeled with the following information:
    a) Patient name
    b) MRN and/or DOB
    c) Medication Name
    d) Dosage
    e) Frequency
    f) Route
    g) Form
    h) Lot # and expiration date
4. Maximum of 30-day supply dispensed at one time.
5. No charges will be assessed for prescription medication samples.

Documenting:

6. Documentation of ordering and dispensing medication as a sample will be made in Epic, including lot number and expiration date.

Recalls:

1. If a medication recall occurs, all patients affected by the recall of the sample medication will be contacted and informed per recall instructions.

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Responsible Area: _____ *Contact Person:_____*

Applies to: Providers and Nursing staff at _____ Effective Date: _____

Last Update: mm/dd/yyyy *Approval Date: mm/dd/yyyy*

Last Review Date: mm/dd/yyyy *Approved by: _____*

Sample Medication Dispensing Log						
Medication:						
Strength:	Route:		Lot Number:		Exp. Date:	
Patient Name	Epic MRN or DOB	Quantity Dispensed	Quantity Remaining	Date Set- up (or N/A)	Date Dispensed	Staff Initials

Appendix E. Rapid Start Clinical Site Checklist

The goal of Rapid Start is to provide immediate ART to clients with HIV at the time of diagnosis (same day if possible) or within 7 days. Everyone in your clinic plays a key role in making this program work. **Is your clinic ready to offer Rapid Start?**

1. **Front-desk staff** are familiar with Rapid Start, are aware that it is provided, understand the time sensitivity of the visit, and are able to triage patient calls and visits accordingly.
2. **Clinical staff** have received training on prescribing rapid/immediate ART.
   A. **Prescribers and nursing staff** are familiar with the Rapid Start Standard Operating Procedures in order to properly prescribe Rapid Start and counsel patients about Rapid Start treatment.

      During a Rapid Start visit, providers should do the following:
      i. HIV history
      ii. Medical history
      iii. Laboratory tests
      iv. ART counseling on the risks and benefits of immediate ART
      v. Initiation of immediate ART
   B. **Social workers, navigators, and counselors** (or other members of the team) can provide psychological counseling and assist patients in navigating insurance coverage and access to other benefits, if necessary.

      During a Rapid Start visit, the following issues also need to be considered:
      i. Insurance navigation if needed (if navigation cannot be done by on- site staff, patient may need immediate referral to an outside navigator)
      ii. Socioeconomic (i.e. employment, housing, etc.) & legal issues (immigration)
      iii. Health issues (i.e. mental health, substance abuse, etc.)
      iv. Other persons at risk for infection (notify partner services)
   C. **Laboratory staff** are prepared to test for HIV antibody, HIV viral load, HIV genotype, CD4+ T cell count, HLAB5701 polymorphism testing, comprehensive metabolic panel (incl. creatinine and liver function tests), RPR, HAV IgG antibody, HBsAg, HBcAb, HBsAb, and HCV antibody on the day of the initial visit. QFT/ toxoplasma IgG antibody and G6PD testing may also be considered.
3. **Participating pharmacies** are prepared to expedite 30 day prescriptions of ART dispense on the day prescribed) and know how to process patient-assistance coupons for antiretrovirals, when needed.
4. The following **resources** are available for patients:
   A. Educational materials
   B. A mechanism for providing same-day ART (e.g., sample/starter packs, same-day enrollment processes for Program HH/ADAP or Medicaid, or pharmaceutical coupons for initial Rx)
   C. A list of pharmacies that are aware of RAPID ART and can provide same- day dispensing