

Purpose: To provide people-centered service and promote community health by reducing barriers to medical care and supporting people with HIV to access treatment immediately. Clinical trials have shown that starting antiretroviral therapy (ART) as soon as possible after diagnosis increases ART uptake, engagement in care and virologic suppression. Using ART to suppress HIV viral loads to <200 copies/mL prevents HIV sexual and vertical transmission, also known as U=U:

Undetectable = Untransmittable.

Rationale: National DHHS guidelines and international WHO guidelines recommend initiating HIV antiretroviral therapy (ART) “immediately or as soon as possible” for all people with HIV, regardless of CD4 count. Initiating ART early and rapidly, especially in acute or recent infection, may reduce the viral reservoir for that individual patient (Jain 2013), preserve CD4 function (Saez-Cirion 2013), increase retention in care (Pilcher 2017, Rosen 2016, Koenig 2016) as well as reduce viral load during a time when the patient may be at highest risk for transmission to others (Coffey 2019, Bacon 2018, Pilcher 2017, Cohen 2011).

The SF General RAPID pilot program, including 86 patients who did not have private health insurance (100%), were non-white (66%), homeless (28%), had mental health disorders (42%), substance abuse disorders (42%) demonstrated shorter time to virologic control (65 vs. 170 days), higher retention at 6 months after diagnosis (90% vs. 85%), and higher rates of ART acceptance (100% vs. 85%) among the 39 patients randomized to rapid ART compared to usual care (Pilcher, JAIDS 2017). Of the 225 patients referred to the SF RAPID program from 2013-17, 96% achieved viral load suppression within 1 year and 92% had durable viral load suppression (Coffey, AIDS 2019). In the international randomized START trial, researchers found that immediate ART had significant improvements in self-assessed quality of life scores (Lifson, AIDS 2017). In the South African RapIT trial (Rosen 2016), people randomized to receive same-day ART had 36% increased uptake of ART and 26% higher rates of viral suppression. A same-day ART randomized study with 762 patients in Haiti showed significantly better 12-month retention in care (54% vs. 42%) and likelihood of being alive (80% vs. 72%) compared to patients in standard care (Koenig, AIDS 2016).

For patients who are not newly diagnosed with HIV but are re-engaging in care, we aim for the intake/orientation appointment and an initial HIV medical visit within 5 days of presenting for care. Data from Project CONNECT (Mugavero, 2008) demonstrated significantly increased linkage to HIV medical care at 6-months when intake/orientation visits were within 5 days of the initial referral call or patient request.

►Rapid ART and warm handoff for patients newly diagnosed with HIV

1. New diagnosis with confirmation and same-day rapid ART linkage: The clinician confirms diagnosis with documentation of a positive HIV viral load, HIV antibody test or 4th generation HIV Ag/Ab test with an HIV 1/2 differentiation, viral load (RNA or NAAT) confirmation. For point-of-care rapid HIV tests, you may wait until the test is confirmed positive to initiate rapid ART, or if there is high probability for HIV infection or suspected acute HIV infection (symptoms, recent exposure), send a viral load (RNA or NAAT). Consider same-day ART before you receive the result.

- a. If there are any questions, the clinician may call the **National Clinician Consultation Center: 800-933-3413**.
- b. **Immediately call the HIV linkage coordinator and/or HIV provider at your care site to coordinate the HIV disclosure, warm handoff and rapid ART linkage process.**
- c. The goal is for the rapid ART intake and clinic orientation appointment to be on the same day as the diagnosis is disclosed to the patient. The testing clinician is responsible for in-person disclosure of the positive test result to the patient, and the linkage coordinator and/or HIV provider can provide support. If the testing clinician is not available in a timely way, the linkage coordinator and intake nurse/provider may also disclose.

2. Obtain baseline labs as soon as the diagnosis is confirmed or if patients are referred

without baseline labs: Please refer to the list of baseline labs on the third page of this protocol. For patients without contraindications to rapid ART, do not wait for lab results to prescribe ART. If ART is prescribed before baseline labs were drawn, we recommend that baseline labs be drawn as soon as possible. The starred labs (★) on page 11 are of highest priority.

3. Same-day disclosure, warm handoff and intake/orientation appointments:

- a. Ideally the HIV linkage coordinator will be available by work cell to meet the patient the same day as disclosure and facilitate a same-day warm handoff to a rapid ART nurse/provider appointment, labs, medication and health insurance coverage assistance.
- b. For patients without insurance, these benefits can often be activated the same-day: Ryan White AIDS Drugs Assistance Program (ADAP).
- c. HIV providers at each site will have at minimum one drop-in slot available each day to accommodate same-day immediate rapid ART linkage appointments. When these drop-in slots are not filled, the same-day appointment can be made available to other patients.
- d. When HIV providers are not available, please schedule same-day appointments for providers willing to prescribe rapid ART. HIV team members are encouraged to support non-HIV providers with this protocol.

4. **Clinical handoff:** The diagnosing clinician, if not the same as the HIV care nurse/provider, provides a care handoff to the HIV nurse/provider in-person, via phone, EHR or HIPAA-secure encrypted email.


5. **Linkage facilitation:** The clinician calls the HIV linkage coordinator who will:


- a. **Arrange for a same-day intake appointment with a nurse or provider who can conduct a brief evaluation and provide a prescription for HIV ART.**
- b. Keep track of the patient to ensure a **warm handoff** and successful linkage to care.
- c. **HIV education counseling and eligibility evaluation:** on the same day as diagnosis, the HIV linkage coordinator provides the patient with an intake, including HIV health education counseling and enrollment for insurance coverage if needed.
- d. **ADAP and/or other medication assistance programs:** If the patient is uninsured or has inadequate insurance to pay for medication, assess eligibility for ADAP (AIDS Drug Assistance Program) and/or other assistance programs and support them in the enrollment process..
- e. Facilitate the patient to receive partner counseling as well as food, housing, transport and other services as needed.


6. During the rapid ART nurse/provider appointment:


- a. The patient's information is entered into the EHR HIV template (if applicable).
- b. The nurse/provider conducts a brief, targeted medical history and exam.
 - i. Ask about current priorities: "What is most important to you right now? How do you want to feel?"
 - ii. HIV history and readiness for treatment: "How do you feel about taking medications for HIV?"
 - 1. Date of last negative HIV test and prior HIV tests
 - 2. PrEP and PEP use history
 - 3. Any other HIV medication use (e.g. ART sold on the street or given by friends or family)
 - 4. Sexual/drug exposures and serostatus of partners. If known to have a partner with HIV, ask if the partner has history of medication resistance
 - iii. Medical history:
 - 1. Co-morbidities, especially renal and liver conditions
 - 2. Medications
 - 3. Drug allergies
 - 4. Review of systems to assess for acute HIV symptoms and opportunistic illnesses
 - 5. If not already obtained, the nurse/provider orders baseline labs (see next page).
- c. Screen for TB and cryptococcal meningitis and if positive, start OI treatment first, then start ART within 2 weeks for TB and within 2-4 weeks for cryptococcal meningitis with close monitoring for immune reconstitution inflammatory syndrome (IRIS).

■ **Recommended Rapid ART regimens: use ICD10 code B20 or Z21.**


Biktarvy®: Bictegravir/emtricitabine/TAF, 1 tab once daily 

Triumeq®: Dolutegravir*/abacavir/lamivudine
(only if HLA-B5701 negative and without chronic HBV), 1 tab once daily 

Dovato®: Dolutegravir/lamivudine (only if HLA-B570 negative. Do not use if HBV coinfection, or HIV RNA >500,000 copies/mL), 1 tab once daily 

Symtuza®: darunavir/cobicistat/emtricitabine/tenofovir alafenamide (For people who used CAB-LA as PrEP and INSTI resistance testing results are not yet available), 1 tab once daily 

Tivicay® + either Truvada® or Descovy®: Dolutegravir* 50 mg+
(TDF 300/200 mg or TAF 25/200 mg), 1 tab each once daily 

Cabenuva®:
Cabotegravir/rilpivirine – long acting injectable ART (injection every 1-2 months)
(Patient should first achieve viral suppression on another regimen before switching to CAB-RPV) 

**For people who are pregnant or have childbearing potential, we recommend counseling patients through informed decision-making regarding the use of dolutegravir and other ARV drugs for people who are pregnant or have childbearing potential. Discuss future reproductive plans and timing with all patients as well as the risks and benefits of conceiving on specific ARV medications and contraceptive options.*

- d. If the patient accepts rapid ART, the provider, or the nurse with precepting provider:
 - i. prescribes a 30-day supply of medication.
 - ii. notifies the pharmacy that the prescription is for immediate fill.
 - iii. notifies the linkage coordinator to follow-up on medication coverage, pick-up and initiation within 1-3 days.
 - iv. schedules a follow-up appointment within 5-7 working days to discuss lab results, assess medication and treatment plan.
- e. If the patient declines rapid ART, use Motivational Interviewing techniques to discuss their reasons and preferences, and schedule a follow-up appointment within 5-7 working days to discuss laboratory results and reassess treatment plan.

► **Baseline labs**

When possible, please order these baseline labs as soon as diagnosis and disclosure is made. The starred labs (★) are of highest priority for safely starting ART, in case the patient would like to split up the lab draws.

Highest priority labs

- ★ If only point-of-care rapid test has been done, order a 4th gen HIV Ag/Ab test
- ★ HIV viral load (RNA or NAAT); CPT code 87536
- ★ CD4 count and %; CPT code 86360
- ★ HIV genotype; CPT codes 87900, 87901, 87906
- ★ CBC with differentiation
- ★ Complete metabolic panel, including renal and liver function
- ★ Hepatitis B sAg
- ★ RPR or VDRL
- ★ Urinalysis with microscopy; you may consider checking microalbumin
- ★ GC/CT NAAT (urethral, vaginal/front hole, rectal, pharyngeal, depending on exposures)

Additional baseline labs

- Hepatitis A total Ab
- Hepatitis B sAb, cAb
- Hepatitis C Ab or RNA if prior treatment
- Lipid profile (non-fasting is fine)
- HgA1C
- VZV IgG
- IGRA
- Toxoplasmosis IgG
- If considering Abacavir: HLA B*5701; CPT 81381
- For some patients: consider urine pregnancy, G6PD levels, CMV IgG, and trichomonas screens.

► Rapid ART for patients re-engaging in care or transferring care

1. If the patient was previously diagnosed but does not have documentation of the test result or past history: if available, conduct a rapid HIV test and draw blood to send an HIV 4th gen Ag/Ab test along with other baseline labs. You may consider a positive rapid test as sufficient proof to start the rapid ART process.
2. **If the rapid test is positive or they have documentation of their HIV diagnosis,**
 - a. **and they HAVE NOT been on ART before** and are willing to start, conduct the intake, baseline labs, brief visit and provide an ART prescription on the same day when possible, following the same steps for newly-diagnosed patients.
 - b. **and they HAVE been on ART before** and can provide the names of their medication and adherence history with some degree of confidence, conduct intake, get baseline labs, sign a release for medical and pharmacy history, contact the pharmacy to verify their most recent ART regimen, facilitate a brief visit and ART prescription on the same day when possible, or as soon as possible within 5 working days. Do not wait for documentation before starting ART. Get INSTI resistance testing with the genotype if the patient has prior INSTI exposure. You can start ART the same day or a few days before you get resistance testing.

► Rapid ART eligibility and medication coverage as of May 2023

1. If the patient is:
 - Insured with affordable co-pay: they are covered; ensure referral to accepting provider.
 - Insured with high co-pay: see co-pay assistance programs below.
 - Use ICD10 codes B20: "Human immunodeficiency virus [HIV] disease" or Z21: "asymptomatic HIV."
2. **Co-pay assistance programs**
 - i. If patient has a high co-pay, Gilead (maker of Biktarvy®, Truvada® and Descovy®) has a co-pay assistance program: gileadadvancingaccess.com, **877-505-6986**
 - ii. Updated co-pay assistance resources can be found on the **NASTAD website**.
4. **Uninsured patients: Patient Assistance Programs for medications:**
 - **Biktarvy®, Truvada® and Descovy®:** The Gilead Advancing Access Program can provide a 30-day supply at no cost for those without coverage, up to 500% FPL: gileadadvancingaccess.com.
 1. Go to the website to download the most current enrollment form.
 2. Follow the directions to complete & submit the form. If you have a Gilead designated agent, call them after 20 minutes.
 3. Gilead can provide a same-day voucher: Fax a letter stating why same-day ART is necessary to the fax number on the form. The letter needs the patient's name, DOB, social security number, date of exposure, any kind of income, household size, and state that it is necessary for new or acute infection.
 4. Call **800-226-2056** (Monday - Friday, 6 am-5pm PST) to get a voucher and bin number to take to pharmacy, and patient should be able to get the medication.
 - **Biktarvy® starter kits**
 1. A Gilead Therapeutic Specialist may be able to provide start kits including 7 pills of Biktarvy® to each facility.
 2. The starter kits are designed to help with each facility's current rapid ART protocol and in situations where the provider has decided a regimen switch is appropriate.
 3. The starter kits can be replenished by calling the Gilead Therapeutic Specialist. There may be limited amount so please discuss with your representatives as to what is an appropriate amount for your facility.
 4. The starter kits must be signed by an HCP-program designated prescribing provider aligned to each clinic at the time of drop off.
 5. Your representative can give you more information as to which HCP provider can sign for the starter kits. If other providers are interested in signing for the starter kits, your Gilead Therapeutic Specialist can submit the appropriate paperwork. The process for adding a new HCP provider can take up to 3 months.

■ Symtuza® starter kits and same-day starter vouchers:

A Janssen representative may be able to provide Symtuza® starter kits for your facility. Contact them to find out.

The Janssen CarePath portal provides online and phone support to obtain same-day pharmacy vouchers for Symtuza® for patients meeting their eligibility requirements: janssencarepath.com/hcp/symtuza

■ Dolutegravir (Tivicay®):

The Viiv Healthcare Patient Assistance Program will provide a same-day voucher for a 30-day supply of dolutegravir at a local pharmacy.

1. Fill out the enrollment form: viivconnect.com/get-started
2. An advocate must call. Any healthcare staff can become an advocate on the same day by calling: **844-588-3288**, 5am–8pm PST, best to call by 4 pm. You will get an advocate number and patient ID to complete the voucher.
3. The patient brings the voucher and the prescription to a local pharmacy.
4. Do not fax the form before the patient picks up the medications. Faxing the form initiates the mail-order refill service and invalidates the initial voucher number. After the patient picks up the first 30-day supply, you can determine if mail order services is needed. If no other medication coverage will be in place for the next fill, then consider faxing the form.

► Rapid ART tracking and Quality Management

1. Track the following dates for each newly diagnosed patient and previously diagnosed patient who is re-engaging in care.



- **Diagnosis/lab result date:** date that HIV confirmatory lab results were available for review.
 - **Referral date:** date when the patient confirmed they want to establish care with your site.
 - **Intake date:** date the patient came in with a confirmed diagnosis to see a member of your team to establish care (e.g. received orientation and eligibility, Ryan White enrollment).
 - **First medical visit date:** date the patient came in to see a clinical provider and received any care related to HIV (does not have to be with an HIV specialist or provider).
- **ART date:** date the patient received the first ART prescription from your site.
 - **Viral load suppression date:** the first date the patient had an HIV RNA viral load <200 copies/ml.

2. Set the rapid ART metrics and goals for the patient population you want to track, for example:

a. San Francisco's RAPID ART definition = diagnosis to visit in 5 days + visit to Rx in 1 day

- **Diagnosis to visit within 5 days** = number of patients whose date of confirmed HIV lab result to the date of first HIV-related medical visit was within 5 days.
- **And visit to Rx (prescription) within 1 day** = number of patients whose date of first HIV-related medical visit to the date of first ART prescription was within 1 day.

b. HIV ACCESS Rapid ART definition = intake to Rx in 1 day

- **Intake to Rx (prescription) within 1 day** = number of patients whose date of intake to date of first ART prescription was within 1 day.

c. New diagnosis rapid ART metric = % of newly diagnosed patients in the last 12 months who meet the rapid ART definition you've chosen (SF's or HIV ACCESS definition above).

d. Re-engagement rapid ART metric = % of patients re-engaging in care and not on ART in the last 12 months whose date of referral to date of ART prescription was within 5 days.

3. Set your goals, time-frame and action plan. Some examples:

- a.** From January 2020 to June 2020, we aim to increase % meeting the SF RAPID new diagnosis definition from 60% to 80% using the steps outlined in this protocol.
- b.** From January 2020 to June 2020, we aim to increase the % for people re-engaging in HIV care with an ART Rx within 5 days of referral using the steps outlined in this protocol.

■ Case example for a newly diagnosed patient with HIV

On 1/9/2020 Berkeley Free Clinic called your team's linkage contact person about a patient who received confirmation for an HIV positive test result on 1/6/2020 and spent the weekend deciding on which clinic to get care. The patient came in to see the linkage coordinator at your clinic on 1/9/2020 and saw a medical provider for an ART prescription on the same day.

Diagnosis date: 1/6/2020 **Referral date:** 1/9/2020

Intake date: 1/9/2020

First medical visit date: 1/9/2020

ART date: 1/9/2020

If the newly diagnosed patient rapid ART metric is defined as time from referral to ART, then this patient meets both the SF RAPID and the HIV ACCESS definition for same-day rapid ART. Her time from diagnosis to medical visit was 3 working days, and the time from medical visit to ART is 0 days (same day). Her time from intake to ART is 0 days (same day).

■ Case example for a patient re-engaging in care

On 1/9/2020 Berkeley Free Clinic called your team's linkage contact person about a patient who's been out of care, re-tested HIV positive and wants to come to your clinic. The patient is not totally sure when he was first diagnosed but is guessing it was 5 years ago at Highland Hospital. He gets on the phone and confirms he wants to be seen at your clinic and provides his contact information to the linkage coordinator over the phone. The patient came in to see the linkage coordinator on 1/10/2020 and saw a medical provider for an ART prescription on the same day.

Diagnosis date: 2013 (estimated)

Referral date: 1/9/2020

Intake date: 1/10/2020

First medical visit date: 1/10/2020

ART date: 1/10/2020

If the re-engaging rapid ART metric is defined as date of referral to date of ART prescription within 5 days, then this patient meets the criteria for re-engaging patients and rapid ART. His time from referral to ART is 1 day.

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