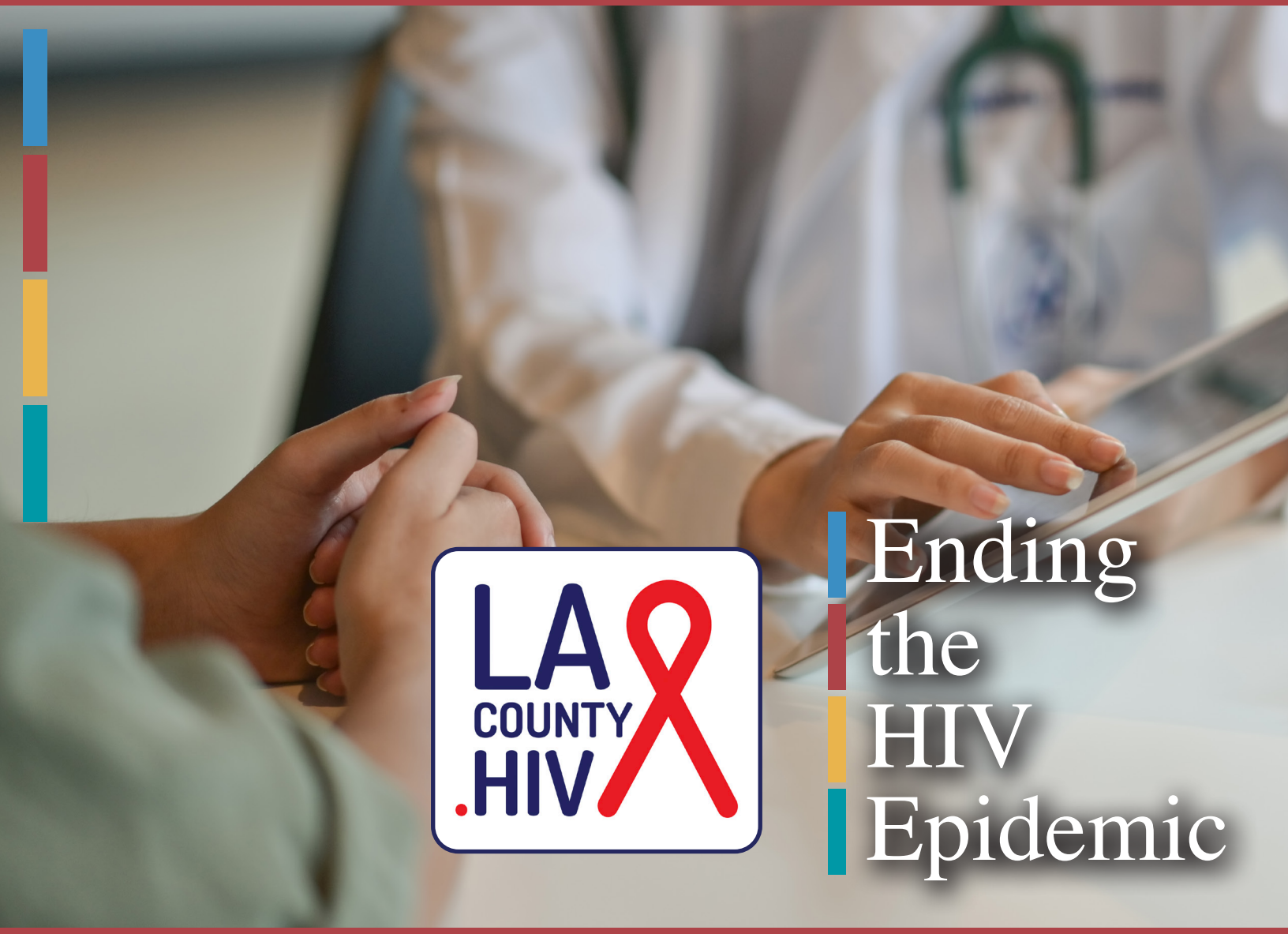


LOS ANGELES COUNTY RAPID AND READY PROGRAM: AMBULATORY OUTPATIENT MEDICINE (AOM) CLINIC GUIDE

2022

County of Los Angeles
Public Health
Division of HIV and STD Programs

Rapid ART:

Immediate antiretroviral therapy (ART) initiation at HIV diagnosis and re-engagement in care

- Allows people to begin treatment sooner.
- Decreases time to virologic suppression by removing barriers to care.

HIV Guidelines advise immediate ART[1,2]

"The Panel on Antiretroviral Guidelines for Adults and Adolescents recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV (AII)."

Immediate ART also benefits the community:

HPTN 052 study and PARTNER studies: NO linked transmissions in male-female or male-male serodifferent couples when the partner with HIV had stable viral suppression on ART.[3,4]

The CDC endorses ART for HIV prevention: "effectively no risk of sexually transmitting the virus" if the HIV viral load is continuously suppressed on ART.[5] This is sometimes referred to as "undetectable equals untransmittable" or "U=U," which means if a person has a viral load that cannot be detected using a blood test, it is not possible for them to transmit HIV to a sex partner.

The San Francisco Experience: A citywide RAPID initiative (2013-2018):[6]

- Faster time from HIV diagnosis to first HIV care visit, to ART initiation, and to virologic suppression.
- Faster ART initiation and viral suppression regardless of race/ethnicity, sex/gender, age, and housing status.

REFERENCES:
(1) HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. December 18, 2019 update. (2) Saag MS, 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. (3) Cohen MS, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. New Engl J Med. 2016 Sep 1;375(9):830-9. (4) Rodger AJ, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet. 2019 Jun 15;393(10189):2428-2438. (5) CDC, Dear Colleague letter, Sept. 27, 2017. cdc.gov/nchhstp/dear_colleague/2017/dcl-092717-National-Gay-Mens-HIV-AIDS-Awareness-Day.html. (6) San Francisco Department of Public Health Population Health Division. HIV Epidemiology Annual Report 2019. Sept. 2020.

Rapid Implementation: Overview

GOAL: First care appointment, known as the "Rapid visit," is within 2 days of referral; start ART at the Rapid visit.

- **Create a single point-of-contact for Rapid referrals:**
  e.g., a Rapid "Officer of the Day" who carries a dedicated pager or cell phone.
- **Form a committed team to handle Rapid roles**
  (Counseling, Benefits Navigation, Clinical/Prescription).
- **Educate entire clinic staff about Rapid**, even if they are not interacting directly with the patient.
- **Minimize hand-offs at the Rapid visit:** Every hand-off should be warm.
- **Develop a plan for medication access*:**
  - ☐ ADAP Temporary Access Program (TAP)
  - ☐ Presumptive Medi-Cal Health-care Insurance
  - ☐ Pharmaceutical Company Patient Assistance Cards
  - ☐ Starter packs of 5-7 days of medication are helpful but are not essential
  - ☐ Partner with a local specialty (HIV) pharmacy to expedite medication dispensing

* Insurance coverage for ART medications is often the biggest barrier to Rapid ART starts; it is important to establish systems for Rapid access to coverage for uninsured persons and to have benefits navigators or social workers with expertise in establishing insurance and medication coverage.

Rapid ART *is* appropriate for:

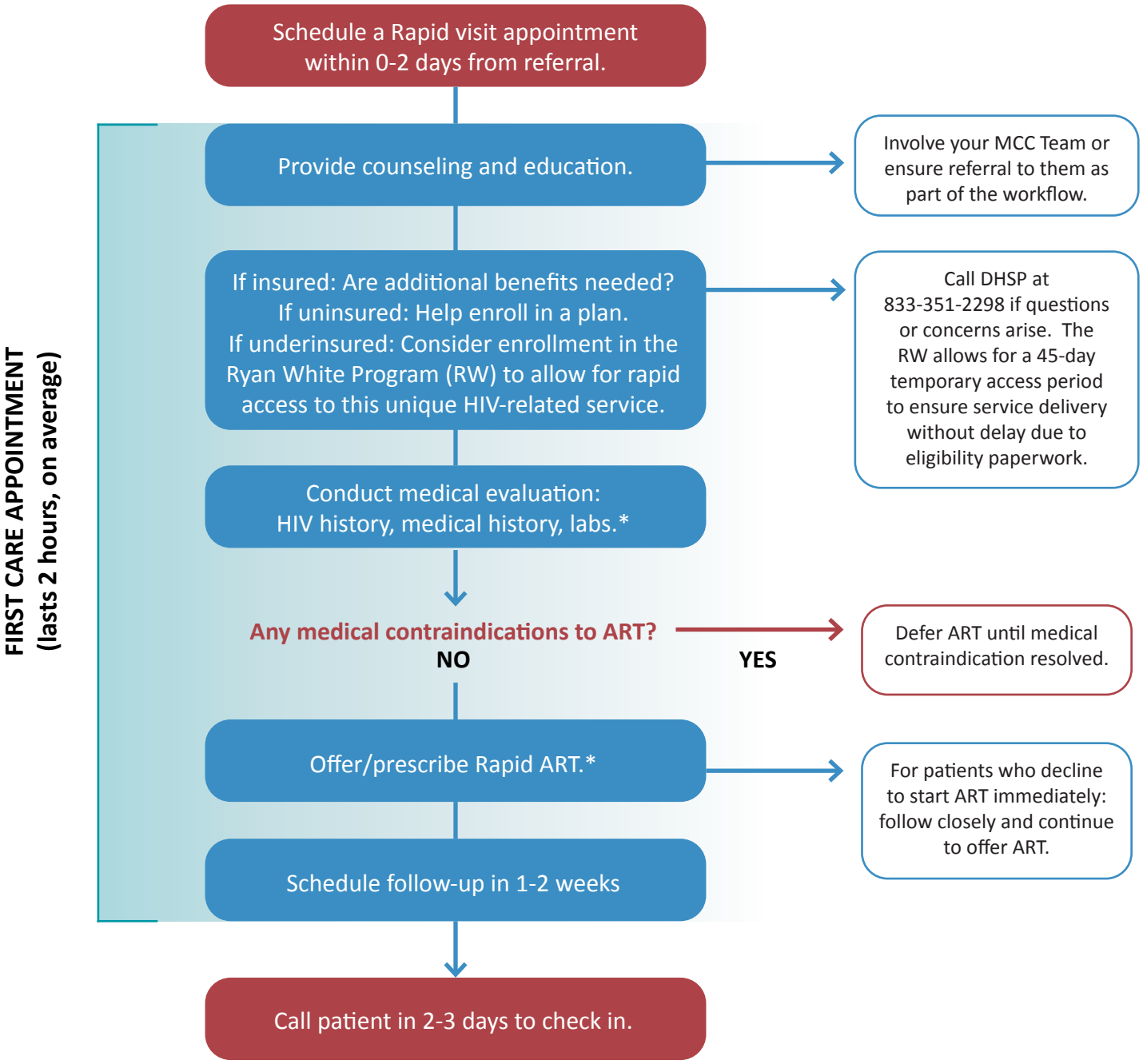
- Anyone with a new HIV diagnosis unless there is a clear contraindication
- Persons with possible acute HIV (see page 5)
- People with HIV who are re-engaging in care: Restart ART immediately if possible and if drug resistance can be predicated and accounted for in the new ART regimen. (see page 8)

Rapid ART is *not* appropriate for:

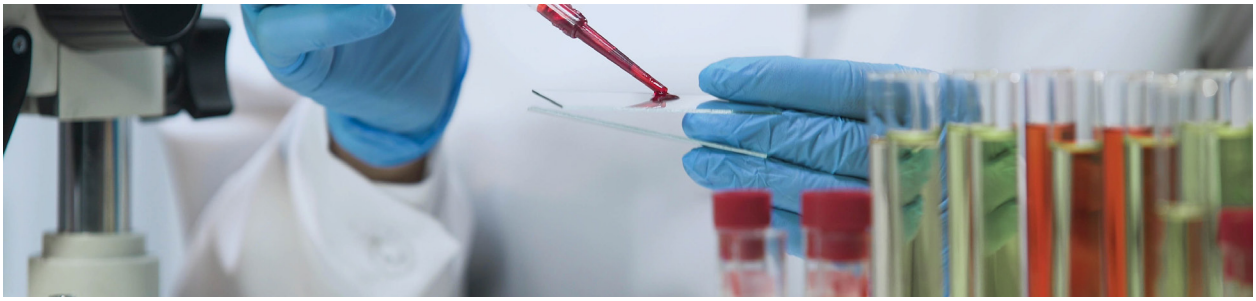
- **Patients for whom immediate ART might be medically dangerous** (e.g., untreated central nervous system opportunistic infections such as cryptococcal meningitis)
- **Patients likely to have multiple ARV mutations** (e.g., treatment experienced with known or suspected resistance) for whom it would be difficult to design an ART regimen without current resistance test results

How to implement Rapid ART at your healthcare facility

RAPID CARE FOR PATIENTS TESTING HIV POSITIVE



* See pages 6-7 for labs and recommended treatment regimens.



HIV Testing

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

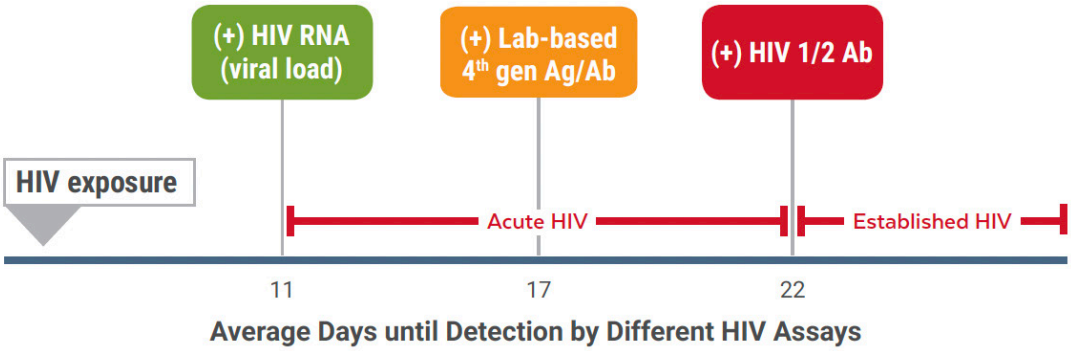
- A confirmed positive test will depend on the testing algorithm used:
  - o reactive lab-based 4th generation antigen/antibody + reactive antibody differentiation
  - o reactive antibody + reactive confirmatory antibody
  - o 2 different reactive single-use rapid antibody tests

Occasionally, a patient will present with:

- Positive HIV RNA (quantitative or qualitative viral load) + non-reactive antibody
  - o 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
  - o 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 initiation before the results of the "tiebreaker" HIV RNA is available.
- One reactive single-use rapid antibody test with confirmation test pending
  - o Indicates either HIV infection or false positive HIV Ab test. If the patient is at risk for HIV infection, consider immediate ART initiation until result of confirmatory test is available. (ART can be stopped if the confirmatory HIV test is negative.)*

*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.

HIV testing during acute vs. established infection



Interpreting HIV test results can be difficult; seek expert advice in cases with discordant test results or complicated clinical scenarios.

Recommended Laboratory Testing and ART Regimens

Laboratory evaluation for Rapid patients

☐ Confirmatory HIV testing *(if needed)*	☐ HAV IgG anitbody
☐ HIV-1 viral load	☐ Hepatitis B serology *(sAb, cAb, Ag)*
☐ HIV genotype, including integrase	☐ HCV anitbody
☐ CD4+ T cell count	☐ Pregnancy test *(if indicated)*
☐ HLA B*5701 plymorphism	☐ Syphilis screening
☐ Comprehensive metabolic panel *(including creatinine and liver function)*	☐ Gonorrhea and chlamydia NAAT at all sites of exposure *(could be urine, vaginal, pharyngeal, rectal)*
☐ Also consider: Quantiferon, Toxoplasma IgG antibody, and G6PD testing. *Can be deferred to subsequen blood draw.*	

Rapid ART treatment regimens

Initial Rapid ART is given before the results of baseline lab testing are available. Thus, it is important to choose Rapid regimens that are likely to be effective even if the most common transmitted resistance mutations are present and if the viral load is >100,000 c/mL. They should have minimal pill burden and side effects.

→ Recommended for most:

OPTION 1

Dolutegravir 50mg

+

TAF/FTC, TDF/FTC, or TDF/3TC

OPTION 2

Bictegravir/TAF/FTC

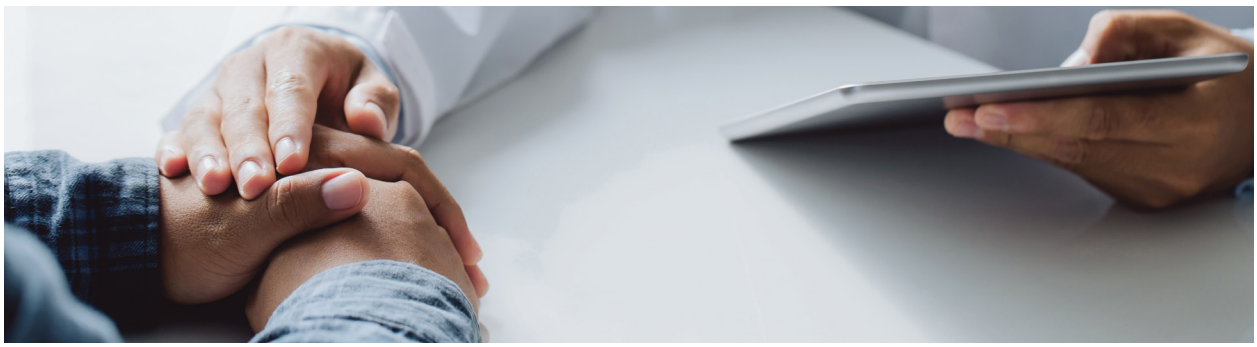
OPTION 3

Darunavir/cobicistat/ TAF/FTC

*Dosing for all options above = **1 pill of each per day***

Note: Regimens can be modified once the results of baseline genotype, HLA B*5701, viral load, serum creatinine, and other tests are available.

Abbreviations: 3TC: lamivudine; FTC: emtricitabine; TAF: tenofovir alafenamide; TDF: tenofovir disoproxyl fumarate



Patients who test positive for HIV while on PrEP

- Take a thorough medication history to determine the last time that they took PrEP, and their PrEP-taking pattern.
- If the patient took any PrEP in the weeks after date of suspected infection, consider starting an enhanced regimen consisting of an INSTI (dolutegravir or bictegravir) + boosted darunavir + TAF/FTC (or TDF/FTC, TDF/3TC) while awaiting results of the genotype.

Pregnancy and Rapid ART

For those who may become pregnant while taking ART:

- Discuss possible risks/benefits of specific ARVs at conception and early pregnancy; choose ART through shared decision making.

For pregnant individuals:

- Dolutegravir 50 mg once daily + (TDF/FTC or TDF/3TC) once daily
- Raltegravir 400mg twice daily + (TDF/FTC or TDF/3TC) once daily

ARVs to *AVOID* until results of genotype, HIV RNA, and HLA-B* 5701 are known:

- **NNRTIs: efavirenz, etravirine, rilpivirine, doravirine, nevirapine**
  - NNRTI class is most associated with transmitted drug resistance.
  - Rilpivirine is less potent if baseline viral load >100,000 c/mL.

- **Abacavir-containing regimens, including co-formulations (Epzicom®, Triumeq®)**
  - High risk of fatal abacavir hypersensitivity reaction if HLA-B* 5701 positive

- **2-drug regimens: dolutegravir/rilpivirine, dolutegravir/3TC, boosted darunavir/3TC, and others**
  - Risk of transmitted drug resistance and virologic failure; not studied as Rapid ART regimens.

Rapid Restart:

For persons re-engaging in care[7]

Immediate ART restart (or initial start, if not previously treated) is appropriate for most persons with known HIV diagnoses who are not on ART, if:

- They are willing and there are no contraindications (see page 3),
- The ART and HIV resistance history is known or can be predicted (based on previous resistance testing, HIV viral load while on ART, and adherence history), and
- An appropriate ART regimen can be devised without information from current resistance test results

» Note that this includes nearly all persons who are re-engaging in care.

» ART restart is particularly urgent for persons with CD4 counts <200 cells/mm³.

» Rapid restart can be done via Telehealth, if indicated.

Provide robust clinical supports to optimize successful re-engagement in care and ART adherence, e.g.:

- Same-day evaluation by a social worker or counselor to assess and address barriers that caused the client to disengage from care.
- Referral for mental health, substance use, or other services as needed.
- Close follow up with the primary care provider.

Laboratory tests:

- HIV RNA, CD4, comprehensive metabolic panel, and other tests as indicated or if not previously done (see page 6).

- HIV resistance test (generally a genotype) should be done, unless new acquired resistance is unlikely (may not be needed if patient had viral suppression at time of ART discontinuation). Include integrase genotype if patient has been on INSTI.

    - o ART can be modified, if indicated, when results are available.
    - o Note: Genotypes obtained when patients are off ARVs may not detect important mutations—consult with an HIV expert.

For patients who do not restart immediately:

- Follow closely (e.g., in 1-2 weeks) and restart ART at the earliest appropriate time.

REFERENCES:

(7) Per Medical Care Coordination (MCC) guidelines, out of care is defined as having not attended an HIV medical appointment in the past 7 months. For persons engaged to care within the past 7 months, an effort should be made to link the patient back to their HIV provider if they agree.

Rapid Restart ART regimens:

Select ART regimens on an individual basis and in consultation with an expert HIV clinician.

Common Rapid Restart ART scenarios:

- **Patient was taking a 1st or 2nd ART regimen, no suspected resistance, consider:** BIC/TAF/FTC; DTG + (TAF/FTC, TDF/FTC, or TDF/3TC); or DRV/c/TAF/FTC; or (unless contraindications) can restart the patient's previous regimen.
- **Patient has known or suspected history of virologic failure with ART resistance:** select the ART regimen based on the suspected resistance mutations. Consult with an HIV expert.
  - **If concern for NRTI resistance with/without NNRTI resistance, consider:** boosted PI + 2 NRTIs ± an integrase inhibitor (e.g., DRV/c/TAF/FTC + DTG).
  - **If concern for NRTI resistance with/without INSTI resistance, consider:** boosted PI + 2 NRTIs ± a 2nd generation NNRTI (if no significant NNRTI resistance) (e.g., DRV/c/TAF/FTC + doravirine).
  - **If more extensive resistance may be present, consider:** multi-class regimen with boosted DRV + an integrase inhibitor ± an NNRTI, fostemsavir, NRTIs, and/or other ARVs, depending on anticipated ARV activity.
- **Pregnancy:** If patient is pregnant or may become pregnant on Rapid Restart regimen, discuss possible risks and benefits of specific ARVs; select regimen through shared decision making.

ARVs to avoid for Rapid Restart:

- 2-ARV regimens, e.g., DTG/3TC, DTG/rilpivirine, cabotegravir + rilpivirine, others (high risk of virologic failure if resistance is present, not studied in this setting)
- Abacavir, unless HLA-B* 5701 is known to be negative

Abbreviations: 3TC: lamivudine; BIC: bictegravir; c: cobicistat; DRV: darunavir; DTG: dolutegravir; FTC: emtricitabine; TAF: tenofovir alafenamide; TDF: tenofovir disoproxyl fumarate

COUNSELING TIPS

1. Check in and offer support

- What questions or concerns do you have as we start the visit?
- How are you doing with this diagnosis? It's often overwhelming at first, but with time, you will realize that you have control of your HIV and that is does not define you.
- Do you know anyone living with HIV? It's like other manageable conditions—you monitor it, take medications daily, and check in with your care team regularly.

2. Destigmatize and normalize

- People from every background and every profession are working and living with HIV.
- Do you know how HIV is (and isn't) transmitted? People who take HIV medications daily and keep their viral load undetectable will not pass it to their sexual partners.
- It is illegal to discriminate against anyone living with HIV.

3. Medical management

- To control your virus and keep yourself as healthy as possible, take your HIV medications every day. Find a time that fits your daily routine to help ensure you do not miss doses.
- Use pill dispensers to keep track of your medications.
- Most people have few or no side effects from HIV medications. If you have any side effects, let us know and we can help you minimize them.

Take Home Messages:

- Form a team and identify one member to serve as the Rapid point-of-contact.
- Ensure patients can access a care appointment within 2 days of referral.
- Draw baseline labs and offer ART to patients at the Rapid visit.
- Discuss how the medications work, the importance of daily adherence, and potential side effects.
- Assess barriers and offer robust clinical supports including referral to MCC.
- Follow up with the patient by phone in 2-3 days, and in the clinic in 1-2 weeks. Subsequent visits should be at 1 month and then at least quarterly until patient is well established in care and HIV viral load is suppressed.

Resources

- For any questions or needs related to the DHSP Rapid and Ready Program:
    - For referrals to a DHSP Rapid Navigator, please call 833-351-2298.
    - For any questions or needs related to the Rapid and Ready Program, please contact Dr. Becca Cohen, DHSP Associate Medical Director, rcohen@ph.lacounty.gov, (323) 914-3055.
- For lost to follow-up clients that are not able to be located:
    - DHSP Linkage and Reengagement Program (LRP) Provider Line: (213) 639-4288.
- The National Clinician Consultation Center (NCCC) has a team of expert physicians, nurses, and clinical pharmacists who support healthcare providers in delivering high-quality care to patients of all ages. Their free and confidential services are for all experience levels.

NCCC HIV/AIDS Management Consultation Line	NCCC Perinatal HIV Consultation Line
(800) 933-3413	**(888) 448-8765**

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