

RAPID START OF ANTI-RETROVIRAL THERAPY (ART) GUIDELINES

- The goal of rapid start is to initiate immediate, within 24-72 hours, anti-retroviral therapy to all patients newly diagnosed with HIV
- Initiating ART during acute/early infection may improve CD4+ T cell recovery, decrease the overall size of the HIV reservoir, and significantly prevent transmission to sexual partners
- Immediate initiation of ART has also been shown to improve linkage to and retention in long-term HIV care

County of Santa Clara Rapid ART Guidelines

Eligibility For Rapid Start

1. Newly diagnosed HIV patients (inclusive of acute and chronic infection)
2. Patient re-engaging in HIV care with low CD4 cell counts (<200 and/or significant co-morbidities)

Exclusion Criteria

1. Patients with signs of serious CNS infection suspicious for meningitis
2. Patients on phenytoin, phenobarbital, oxcarbazepine, carbamazepine, rifampin, rifabutin, enzalutamide, St. John's wort or any strong inducer of CYP3A4
3. Patients with a history of allergic reaction or intolerance to Bictegravir or emtricitabine or tenofovir alafenamide or the combination product Biktarvy®.
4. Patients who are pregnant or breast feeding or are planning pregnancy
5. Patients without documented positive HIV test result of any kind

Recommended Regimen for Rapid ART

Bictegravir/Tenofovir Alafenamide/Emtricitabine (Biktarvy®) 50/25/200 mg tablet

Take one tablet by mouth once daily.

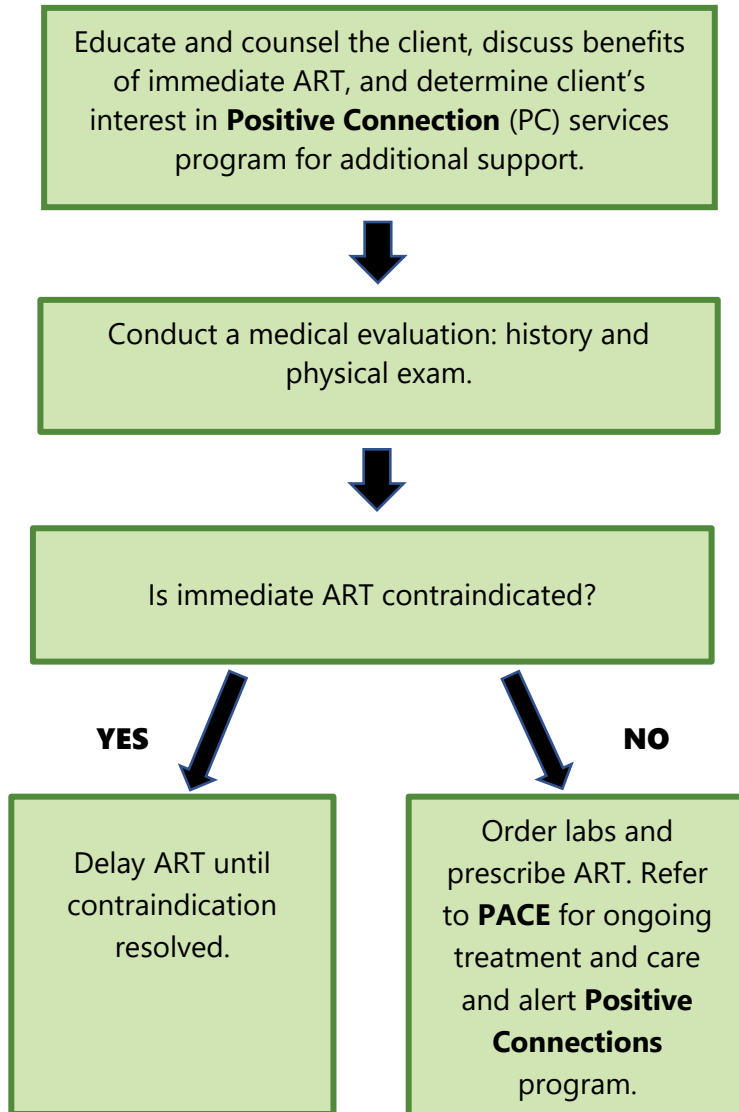
Side Effects of Biktarvy

- Diarrhea
- Headache
- Abnormal dreams
- Nausea
- Fatigue
- Dizziness

Serious but uncommon side effects: signs of kidney problems, signs of liver problems, loss of appetite, stomach/abdominal pain, slow/irregular heartbeat, blue/cold skin, muscle pain

SAMPLE RAPID ART WORKFLOW AND CONFIRMATORY LAB TESTS FOR PATIENTS TESTING HIV POSITIVE

Confirmatory Laboratory Tests



Rapid ART Workflow

<i>To Be Ordered on the Day of Therapy Initiation</i>
HIV-1 and HIV-2 antibodies, P24 Antigen
HIV-1 RNA, quantitative PCR
HIV1 Genotype
CD4 (aka CD4)
HLA-B*5701 Typing
Syphilis (FOR INITIAL DIAGNOSIS)
GC and Chlamydia Triple Screen ** (Order Panel) **
Hepatitis C antibody (aka ANTI-HCV)
Hepatitis B surface antigen (aka HBSAG)
Hepatitis B core antibody... (aka ANTI HBC)
Hepatitis B surface antibody (aka ANTI-HBS)
QuantiFERON
Toxoplasma gondii antibody, IgG
Glucose 6 phosphate dehydrogenase... (aka G6PD)
Anti-HAV, IgG
Liver function test (aka LFT)
Panel 7 (aka P7)
Hemogram with differential (aka CBC)
Urinalysis
**Testing for Gonorrhea and Chlamydia at three sites (oral, anal, urine) is recommended for sexually active MSM; Rectal and Oral swabs are ordered as clinic collect

Positive Connections Program:

The Positive Connections Program provides comprehensive case planning and coordination for those individuals who have been newly diagnosed with HIV or are not currently in care in Santa Clara County ([Positive Connections](#)).
Phone: [\(408\) 792-5080](tel:4087925080)

Partners in Aids Care and Education (PACE) Clinic:

PACE offers a multi-disciplinary approach to care in all stages of HIV infection ([PACE](#)).
Phone: [\(408\) 885-5935](tel:4088855935)

ART CONTRAINDICATIONS

Immediate 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

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

Patients with positive HIV test 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.

Antiretrovirals (ARVs) to Avoid Until Results of Genotype, HIV RNA, and HLA B*5107 Are Known:

- **NNRTIs (efavirenz, etravirine, rilpivirine, doravirine, nevirapine)**
 - Transmitted drug resistance to NNRTI class is most common.
 - Rilpivirine is less potent if baseline viral load >100,000 c/mL.
- **Abacavir-containing regimens, including co-formulations (Epzicom[®], Triumeq[®])**
 - High risk of abacavir hypersensitivity reaction if HLA B*5701(+)
- **2-drug regimens: dolutegravir/3TC (Dovato[®]), dolutegravir/rilpivirine (Juluca[®]), cabotegravir + rilpivirine (Cabenuva[®]), boosted darunavir + 3TC, and others**
 - Risk of transmitted drug resistance and virologic failure; not well studied as RAPID regimens