

Test and Treat and Retain in Care Guidance

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FLORIDA DEPARTMENT OF HEALTH

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At A Glance
Test and Treat Initiation Overview for County Health Departments
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One goal of the Florida Department of Health (DOH) is to ensure persons diagnosed with HIV are started on antiretroviral therapy (ART) as soon as possible and that persons living with HIV stay on ART consistently to obtain and sustain a suppressed viral load.

This guidance presents an overview of relevant information for clinicians, including physicians, physician assistants, nurse practitioners, and registered nurses, who are providing Test and Treat (T&T) in clinical settings. Important considerations for starting and monitoring a patient on T&T are presented below.

Getting Started:

T&T is indicated for the following individuals:

- newly diagnosed HIV patients (positive screening test or confirmed positive test)
- patients who have already been in care for HIV but have experienced a gap in their treatment and are returning to care

Components of a T&T intervention:

- Facilitation of same day or next day appointments using flexible scheduling options such as onsite or telehealth appointments.
- Available onsite ART through issuance program/samples/medication vouchers
- Process to link clients to a full-time health care provider for both primary care and HIV-specific healthcare needs
- Process to refer client for assistance with Ryan White eligibility/health insurance coverage and case management services

T&T Services Timeline:

Day one (or within a few days):

- Clinician visit to assess brief medical history and concomitant medication review, targeted exam, psychosocial needs, risk reduction, ART education, and regimen selection
- Obtain baseline labs (see below for list of labs required); can be ordered prior to visit or on same day that ART is started
- Provide linkage to HIV primary care within 7 days of T&T visit
- Schedule follow-up appointment if patient will be receiving HIV primary care at current county health department (CHD) location

Day 3-10 (Follow-up)

- Call/or email through DOH approved patient portal to check on patient (recommend at 3-4 days post-ART start)
- Review baseline labs with patient, may be completed in person or over the phone with patient consent
- Order opportunistic infection (OI) prevention medication as indicated (See FAQ for details)
- Adjust ART as needed/indicated

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Day >30 (Follow-up)

- Monitor/ensure compliance with follow-up labs and appointments
- For those CHDs not providing HIV care, document in Health Management System (HMS) the provider assuming care and appointment date (be sure the consent form is signed by the patient to send record to the provider outside the CHD).

Required Minimum Baseline Laboratory Tests for Initial T&T Services:

- HIV 1/2 Antigen/Antibody (Ag/Ab), 4th generation blood-based test, if indicated
- Absolute CD4 count with the percentage of CD4 cells
- Viral Load HIV-1 Ribonucleic Acid Polymerase Chain Reaction (HIV-1 RNA PCR) Quantitative
- HIV-1 Protease (PI) and Non/nucleoside Reverse Transcriptase (N/NNRTI) Genotype Resistance Test
- Hepatitis Panel or at a minimum: hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb)
- Comprehensive Metabolic Panel (CMP) (ALT, AST, creatinine with estimated glomerular filtration rate [eGFR])
- Urinalysis macro, or point of care (POC) urine dipstick for protein
- Rapid Plasma Reagin (monitor) with reflex to titer
- Pregnancy test (all women of child-bearing potential)

(Please refer to the chart on page 10 for additional information on tubes and coding for above lab tests)

Recommended Regimens:

30-day ART regimens for T&T (listed alphabetically):

- Bictegravir/tenofovir alafenamide/emtricitabine (Biktarvy[®]) one (1) tablet once daily **with or without food** (available through samples or issuance program)

OR

- Darunavir/cobicistat/emtricitabine/tenofovir alafenamide 800/150/200/10 mg (Symtuza[®]) one (1) tablet once daily **with food** (available through voucher, or issuance program)

OR

- Dolutegravir 50 mg one (1) tab once daily (Tivicay[®]) with tenofovir alafenamide 25 mg/emtricitabine 200 mg (Descovy[®]) one (1) tablet of each once daily, both taken **with or without food**

Note: In cases of known resistance, at the provider's discretion, combinations of PI/Integrase Inhibitor (INSTI) plus or minus NRTI may be dispensed.

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30-day ART for women intending to conceive (use in other circumstances allowable):

- Raltegravir 400 mg (Isentress®) one (1) tablet twice daily with tenofovir disoproxil fumarate/emtricitabine 300/200 mg (Truvada®) one (1) tablet daily, both **with or without food**

30-day ART throughout pregnancy and an alternative recommended regimen for women trying to conceive:

- Dolutegravir 50 mg one (1) tab once daily (Tivicay®) with tenofovir disoproxil fumarate /emtricitabine 300/200 mg (Truvada®) one (1) tablet of each once daily, both taken **with or without food**

Note: INSTIs can interact with medications containing polyvalent cations including prenatal vitamins. See table below:

INSTI Interactions with Polyvalent Cations			
	Bictegravir (BIC)	Dolutegravir (DTG)	Raltegravir (RAL)
Antacids (e.g., Al, Mg, Ca)	<ul style="list-style-type: none"> • Take BIC \geq 2 hours before or \geq 6 hours after antacids containing Al or Mg • Take BIC with antacids containing Ca with food 	<ul style="list-style-type: none"> • Take DTG \geq 2 hours before or \geq 6 hours after antacids containing Al, Mg, Ca 	<p>With calcium carbonate antacids:</p> <ul style="list-style-type: none"> • No dosage adjustment or separation needed with RAL 400 mg bid • Do not use once daily RAL HD formulation with calcium carbonate antacids <p>With Al and/or Mg containing antacids:</p> <ul style="list-style-type: none"> • Do not combine
Polyvalent cation (e.g., Al, Ca, Fe, Mg, Zn) containing medications including multivitamins, supplements, laxatives, sucralfate and buffered medications	<p>Supplements containing Ca or Fe:</p> <p>Take simultaneously with food or if fasting, take BIC \geq 2 hours before other polyvalent cations:</p> <p>Take BIC \geq 2 hours before or \geq 6 hours after (based recommendation for other INSTI)</p>	<p>Supplements containing Ca or Fe:</p> <ul style="list-style-type: none"> • Take simultaneously with food or if fasting, take DTG \geq 2 hours before or \geq 6 hours after • Other polyvalent cations: • Take DTG \geq 2 hours before or $>$6 hours after • \geq 6 hours after 	<ul style="list-style-type: none"> • Take RAL \geq 2 hours before or \geq 6 hours after polyvalent cation containing supplements

Frequently Asked Questions

General:

Q: Can our CHD participate in T&T if we don't have an onsite HIV clinic?

A: Yes. Providers in Sexually Transmitted Diseases (STD), adult health and family planning clinics can be trained to initiate HIV medications.

Q: If our CHD does not have on site clinician available or the clinician has not provided HIV medications before, are we able to participate in T&T for our communities?

A: Yes, your CHD can access the telehealth T&T clinicians and your patient can be seen at your local CHD or in the privacy of their home over a face to face HIPPA compliant computer connection (See Telehealth T&T process). Patients will need to have an HMS electronic health record opened and vital signs completed. The telehealth clinician will document the care in your CHD's instance of HMS including completing the Issuance Program medication documentation. A member of your CHD team will then need to arrange for the draw of initial laboratory specimens, provide issuance program medication, and link to ongoing HIV care within your community. The telehealth clinicians will assess the laboratories drawn at the baseline visit and discuss with a member of your CHD onsite team.

Q: What ICD10 code should be used for T&T visit?

A: For a patient presenting with history of an AIDS diagnosis, use B20. Otherwise at these initial visits use Z21 to denote a diagnosis of asymptomatic HIV infection when you have a confirmed 4th generation HIV test result and R75 when you have a positive 3rd generation rapid test not yet confirmed.

Q: How do I obtain issuance medication?

A: Issuance medication is obtained from on-line PHS pharmacy (central pharmacy). If you do not have access to the on-line ordering system, refer to your CHD nursing director for guidance.

Q: How do I obtain pharmaceutical samples?

A: Contact the pharmaceutical representative assigned to your county. Please check the County Health Systems SharePoint site for Public Health Practice for rosters to pharmaceutical representatives in your area.

floridahealth.sharepoint.com/sites/COUNTYHEALTHSYSTEMS/PHPU/SitePages/Home.aspx

Q: What opportunistic infections (OI) should I be concerned about?

A: Please see the guidelines listed here for an introduction to OI and treatments
aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/392/whats-new

Insurance:

Q: If my patient has insurance, are we able to provide T&T medications?

A: The best practice is to e-prescribe the medication to the pharmacy of the patient's choice and then call and speak with the staff at the pharmacy. Ask the staff to run the medication to see if a prior authorization is required. If prior authorization is required, or it will take more than a day to

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get the medication into the pharmacy, provide T&T issuance program antiretroviral regimens to support the patient's initial therapy

Q: What if the patient has an insurance plan for which our provider is not eligible for reimbursement?

A: The answer to this question is decided at a local CHD level. Your CHD may support treatment initiation for out of network insured patients. In some instances, if the patient agrees, you can discuss their case with an in-network provider and collaborate to initiate lab and medication needs for the patient. In some instances, the insurance may not reimburse at as high of a level when the provider is "out of network" but the reimbursement may be adequate to cover the costs of the T&T evaluation (CHD provider time and lab cost). If your CHD is not able to see the patient related to payer source, assist with immediate linkage to a provider in network.

Labs:

Q: Is a confirmed HIV test required before patients can present for T & T evaluations?

A: No, a patient should be offered a T&T evaluation based upon finding an initial HIV positive screening test. The T&T clinician will make determination as to the likelihood of a potential false positive test and may wait to initiate T&T until the confirmatory 4th generation blood-based HIV test results. When the history or at-risk behaviors support the likelihood the screening HIV test will be confirmed positive, the patient should proceed through the T&T evaluation process and initiate antiretroviral therapy.

Q: What if the patient's lab returns a positive Hepatitis B Surface Antigen test result?

A: Your patient has hepatitis B infection. Each of the T&T regimens contains two active drugs against hepatitis B: tenofovir alafenamide/emtricitabine or tenofovir disoproxil fumarate/emtricitabine. The patient should be informed they need further evaluation with their primary care provider. It should be stressed to not stop taking their antiretroviral (ARV) medication as serious flares of hepatitis B have occurred when treatment was abruptly stopped. Once the hepatitis B Surface Antigen is known to be positive, the patient should be contacted, and test results should be sent to the patient's primary care provider with consent of the patient.

Medications:

Q: Is the patient taking concomitant drugs or drugs that may interact with one or more of the T&T medications?

A: Obtain a thorough medication history including over the counter medications. Drugs that may impair renal function (such as nonsteroidal anti-inflammatory drugs) may interact with tenofovir disoproxil fumarate containing regimens. Drugs that induce p-glycoprotein (such as carbamazepine, oxcarbazepine, phenytoin, rifabutin, rifampin) may interact with tenofovir alafenamide-containing regimens. Polyvalent cations may interact with INSTI containing regimens (see table above). Cobicistat (component of Prezcoibix® and Symtuza®) is a boosting agent and can interact with many drugs, primarily through inhibition of CYP3A4, CYP2D6, and P-glycoprotein.

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Use aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview to check for possible drug-drug interactions.

Q: How do you counsel the patient on the use of their ARV medications?

A: Provide patient instructions on how to take their medications including whether the medications need to be taken with food. Instruct patient on the importance of taking the medications at the same time each day; however, a patient does not need to stick with the time they took the first dose of medication at the T&T visit if that time is not the best time for him/her to remember to take the medication. Counsel the patient on the importance of not missing any dose and the relationship of missing doses to the development of resistance which could make the virus more difficult to treat and require the use of more medications. Counsel the patient on the importance of not running out of their medications, contacting the pharmacy in advance for refills, and available resources to assist them in obtaining their medications should they have no insurance or have copays or premiums that they cannot afford.

Use the HIV Medication Information Sheets from the North Florida AIDS Education and Training Center at aetc.medicine.ufl.edu/resources/drug-information-sheets/ to assist in educating patients about their ARV regimen.

Q: What if a patient returns to us and states he/she cannot obtain their medication?

A: No patient is to be turned away without medication if it is at all preventable. Provide the patient with samples or issuance program medication while the issue is addressed. Refer patient to the Florida AIDS Drug Assistance Program for assistance for uninsured clients or clients with insurance who need premium and/or copay assistance. Pharmaceutical copay cards can be used to pay for copays for patients with private insurance. Other programs (e.g., Good days at mygooddays.org/ or Patient Advocate Foundation at patientadvocate.org/) are available to assist patients with federally-funded insurance (i.e., Medicare, Medicaid, Tricare). Consider use of a local or mail order specialty pharmacy that may assist you in making sure patients with insurance can maintain access to their ARVs. Consider referral to a Ryan White case management organization.

Ryan White:

Q: If eligibility for Ryan White is not completed before the patient runs out of ART, can the T&T program use the issuance program to provide additional ART to prevent a lapse in medication?

A: Yes, the goal is to ensure no patient in need of ARV medication goes without.

Q. If your CHD does not have a relationship with a Ryan White Lead Agency how are services reimbursed?

A: Services can be paid through several options depending on the client's situation.

1. Bill client's insurance
2. Client's self pays
3. CHD establishes a purchase order/contract with the local Ryan White Lead Agency to be reimbursed (for Ryan White eligible clients only)

For a T&T visit, most expenses are related to clinician time, medication and lab tests. Where a client does not have the means to self-pay or the CHD cannot bill the client's insurance, services will have to be covered with local funds.

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- Medication can be provided free of charge to the client through the DOH Issuance Program or providers can use samples or vouchers.
- Clinician time provided through the HIV Telehealth Program has no cost to the CHD. Local clinician time will have to be covered with local fees.
- Lab costs are typically where there is a challenge in finding funding.

Special Populations:

Q: How do we address the high-risk patient who presents with Acute Viral Syndrome symptoms?

A: Take a thorough health and sexual history, evaluating high-risk activity of the patient and partner(s). Perform a rapid HIV test and draw blood for a 4th generation HIV test. If the patient's high risk exposure was within the last 15 days, draw an HIV-1 PCR RNA Viral load. Initiate post exposure prophylaxis with one of the T&T regimens and follow up as per post exposure prophylaxis guidance. Discuss safe sex practices while awaiting test results and follow-up. hivguidelines.org/pep-for-hiv-prevention/

Q: What if the patient is pregnant or planning pregnancy, or not on adequate birth control?

A: Always refer to the latest update of the Department of Health and Human Services (DHSS) Perinatal guidelines (aidsinfo.nih.gov/guidelines/html/3/perinatal/488/overview) Prezcofix[®], Descovy[®], and Biktarvy[®] are not recommended for use in pregnancy. Tivicay is a preferred ARV option throughout pregnancy and **an alternative ARV** for women who are trying to conceive used in combination with Truvada[®]. For women trying to conceive, Truvada[®] and Isentress[®] (raltegravir) are available options. Truvada and Tivicay are available as an alternative regimen.

Q: How do you evaluate a patient that presents with a positive 4th generation HIV antibody test result whose HIV-1 viral load returns an undetectable result?

A: In the case of an individual presenting with a positive HIV antigen/antibody combination assay who is then found to have an undetectable HIV viral load, one must consider the possibility of a false positive HIV 4th generation test. The fourth generation HIV assay specificity is greater than 99.6 percent. For every 10,000 tests performed, as many as 40 may be false positive. False positive test results have been reported during pregnancy. When the HIV viral load returns an undetectable HIV-1 result, repeat the test to confirm and assess the patient's history to determine if he/she would be considered at low risk for HIV infection. Consider the patient may have been on ART at the time of the viral load draw. Inquire as to any memory of signs and symptoms that may have been consistent with acute HIV seroconversion.

To differentiate between a false positive HIV 4th generation test versus a PLWH who is an elite controller (long-term non-progressor, less than 1% of PLWH), performing whole-blood HIV-1 proviral DNA qualitative testing is recommended (Amplicor HIV-1 DNA Test, Roche Molecular Diagnostics). This test identifies proviral DNA within the host cell genome which can be detected in the absence of viral replication. If positive, the patient is an elite controller of HIV infection and would benefit from ART.

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[Case Example: HIV-1 in pregnancy with undetectable viral load](#)

Telehealth Resources:

Telehealth services for T&T are available. Equipment costs are minimal and include a CHD computer with video camera and speakers. For Telehealth, HIPAA compliant Skype for Business or Polycom is used and is provided to the CHD at no cost. When anticipating a telehealth T&T patient please call, e-mail or Skype, one of the following staff by starting with the first number in the list below and progressing downward:

1. Telehealth APRN – 239-770-6277
2. Telehealth Provider back-up - (904) 253-1731 x 1731
3. Administrative Assistant (O) 239-656-2501, (M) 239-292-3054
4. HIV AIDS Section Medical Director – 850-519-3734

One of the clinicians noted above will accept the telehealth session and will be the one with whom you establish an audiovisual (AV) connection. A calendar invite will be sent to the contact person at the originating site, with the date and time of the visit and the name of the provider seeing the patient. Before each Telehealth encounter, test the AV system and problem-solve any connection issues.

Additional guidance:

- HIV/AIDS related medical practice guidelines including Adult ARV, Perinatal, and Adult OI guidelines. aidsinfo.nih.gov/
- Clinician Consultation Center nccc.ucsf.edu/clinician-consultation/hiv-aids-management/
- Antiretroviral Drug Interactions hiv-druginteractions.org/
- Antiretroviral Patient Medication Information Sheets. aetc.medicine.ufl.edu/resources/drug-information-sheets/

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Laboratory Test Quick Reference:

TEST NAME	TUBE	TEST CODE	TEST CODE	TEST CODE
		QUEST	STATE	LAB CORP
HIV 1/2 Ag/Ab, 4 th gen (if no record of 4 th gen)	SST	91431	0500	083935
HIV-1 RNA, Quantitative Real Time PCR Viral Load	White top tube	40085	0560	550420
HIV-1 Genotype (RT, PR)	White top tube	34949	0000570	551697
Comprehensive Metabolic Panel (14)	SST	10231	Does not run Test	322000
Hepatitis Panel (HAV, HBV, HCV*)	SST	6462	0380	303744
CBC (Includes Diff/PLT)	Lavender	6399	Does not run Test	005009
Lymphocyte Subset Panel 5 (Absolute CD4 & CD4% Panel 5)	Lavender	8360	000540 (CD4 and CD8 only)	505008
Urinalysis Macroscopic Urinalysis (POC dipstick)	Yellow top tube CHD	6448	Does not run Test	003772