HIV Pre-Exposure Prophylaxis (PrEP) Clinical Guidelines

PREPARED BY
THE HIV/AIDS SECTION MEDICAL TEAM
BUREAU OF COMMUNICABLE DISEASES
DIVISION OF DISEASE CONTROL AND HEALTH PROTECTION
FLORIDA DEPARTMENT OF HEALTH

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One goal of the Florida Department of Health is to reduce the number of new HIV diagnoses in the state of Florida. Biomedical interventions are available that allow an individual to take medication that will significantly reduce their risk of acquiring HIV. This is called pre-exposure prophylaxis, or PrEP.

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

Prior to starting an individual on PrEP, the HIV status of the individual must be ascertained. This can be done using a confirmatory HIV test result received within the past seven days or with a negative rapid HIV test at time of PrEP initiation and a blood-based confirmatory test drawn at the same time. The person should also be free of any signs or symptoms of acute HIV (detailed in the Frequently Asked Questions section beginning on page 11).

All Food and Drug Administration (FDA) approved options for PrEP should be discussed with patients presenting for PrEP services.

PrEP IS INDICATED ONLY FOR HIV-NEGATIVE INDIVIDUALS.
All sexually active adult and adolescent patients should receive information regarding sexually transmitted infections (STIs), PrEP and non-occupational, post-exposure prophylaxis (nPEP).

Department of Health employees may not provide PrEP prescriptive services to persons under the age of 18 without parental consent.

PrEP is FDA approved for adults and adolescents weighing at least 35 kilograms (77 pounds) who are at risk of HIV acquisition through sexual activity or injection drug use. Risks associated with HIV acquisition:

- Not being in a monogamous sexual relationship with a partner who is HIV negative.
- Injecting drugs and/or sharing needles or works or being sexually active with a partner who injects drugs and/or shares needles or works.
- Having unprotected sex with a partner living with HIV who is not consistently virally suppressed.
- Not using condoms consistently or correctly.
- Being sexually active with one or more partner with HIV risk factors or unknown HIV status.
- Having a history of STIs by lab testing or self-report or syndromic STI treatment.
- Identifying as at ongoing risk of HIV acquisition likely to continue at the end of nPEP therapy (please see section on transitioning immediately from nPEP to PrEP).

Injectable PrEP has not been studied in men or women under 18 years of age. These studies are underway, but until safety is determined for this population and reviewed by the FDA, cabotegravir is not recommended for adolescents.

Oral PrEP is FDA approved for adolescents, and Department of Health policy allows administration of oral PrEP to adolescents for whom parental consent can be obtained.

ORAL MEDICATIONS FOR PrEP

- Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC)(F/TDF) fixed dose combination (Truvada) and tenofovir alafenamide (TAF)/emtricitabine (F/TAF) fixed dose combination (Descovy) are approved by the FDA for use as PrEP in combination with safer sexual practices and harm reduction to reduce the risk of individuals acquiring HIV.
- Clinical trial data shows Truvada for PrEP to be an effective HIV prevention strategy for all patients adherent to taking oral PrEP medication every day.
- Clinical trial data shows Descovy for PrEP to be an effective HIV prevention strategy for persons exclusively having anal receptive and insertive sex.
- Descovy is NOT indicated for use as PrEP in persons having receptive vaginal sex.

Generic Name	Trade Name	Dose	Frequency	Most Common Side Effects
F/TDF	Truvada	200 mg /300 mg	Once a day	Headache, abdominal pain, nausea, back pain, weight loss, mild decrease in renal function
F/TAF	Descovy	200 mg /25 mg	Once a day	Headache, abdominal pain, nausea, back pain, weight gain, elevations in triglycerides and/or cholesterol, mild decrease in renal function

Contraindications to Oral PrEP:

- HIV-positive status.
- Estimated creatinine clearance less than 60 mL/min and/or weight less than 77 pounds for F/TDF.
- Estimated creatinine clearance less than 30 mL/min and/or weight less than 77 pounds and/or having vaginal sex for F/TAF.
- Unwillingness or inability to take a pill every day or follow up every 3 months for lab work for F/TDF and F/TAF.
- Signs/symptoms of acute HIV infection.
- Allergy or contraindication to any medicine in the PrEP regimen.
- History of recent high-risk exposure— should be considered for nPEP before initiating PrEP.

Drug Interactions with Oral PrEP, F/TDF:

- FTC and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion.
- No drug-drug interactions due to competition for renal excretion have been observed; however, co-administration of F/TDF with drugs that are eliminated by active tubular secretion may increase concentrations of FTC, tenofovir and/or the co-administered drug. Some examples include, but are not limited to, acyclovir, adefovir dipivoxil,

cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides (e.g., gentamicin) and high-dose or multiple nonsteroidal anti-inflammatory drugs (NSAIDs).

- Drugs that decrease renal function may increase concentrations of FTC and/or tenofovir.
- Monitor patients taking certain protease inhibitors (atazanavir, lopinavir/ritonavir, atazanavir/ritonavir and darunavir/ritonavir) and hepatitis C antiviral agents (sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir and ledipasvir/sofosbuvir).
- Please see package insert for full prescribing information.

Drug Interactions with Oral PrEP, F/TAF:

- TAF, a component of F/TAF, is a substrate of P-gp, BCRP, OATP1B1 and OATP1B3. Drugs that strongly affect P-gp and BCRP activity may lead to changes in TAF absorption.
- Drugs that induce P-gp activity are expected to decrease the absorption of TAF, resulting in decreased plasma concentration of TAF, which may lead to loss of therapeutic effect of F/TAF and development of resistance.
- Co-administration of F/TAF with other drugs that inhibit P-gp and BCRP may increase the absorption and plasma concentration of TAF.
- TAF is not an inhibitor of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 or UGT1A1.
- TAF is a weak inhibitor of CYP3A in vitro.
- TAF is not an inhibitor or inducer of CYP3A in vivo.
- Co-administration with tipranavir/ritonavir, rifabutin, rifampin, rifapentine and St. John's wort is not recommended.
- TAF concentration decreases with carbamazepine, oxcarbazepine, phenobarbital and phenytoin. Consider an alternative anticonvulsant.
- Please see package insert for full prescribing information.

Key Effectiveness Messages for Oral PrEP:

- When using F/TDF for receptive vaginal sex and injection drug use, maximum protection occurs in about 20 days of daily dosing. For receptive anal sex, this is 7 days. We do not yet have similar data points for F/TAF, but research has shown F/TAF to have a more rapid onset, higher levels of tenofovir diphosphate in HIV susceptible immune cells and longer sustained duration of protection than F/TDF.
- Oral PrEP is highly effective for preventing HIV infection when taken every day as prescribed.
- Oral PrEP does not prevent pregnancy or STIs.

Side Effects, Oral PrEP:

- PrEP pill users may have side effects such as nausea, abdominal cramps and headache; these are usually mild and resolve over the first few weeks of taking PrEP.
- Use of F/TDF and F/TAF for PrEP may cause mild reductions in renal function.
- F/TAF was associated with higher rates of triglyceride elevation and weight gain compared to F/TDF.

- F/TDF users may also experience decreased bone mineral density (1 percent average loss of bone mineral density), which in clinical trial assessment stabilized or returned to normal in the first months of therapy and was not associated with increase in fractures.

Intermittent Oral PrEP Regimen for Men Who Have Sex with Men (2-1-1 PREP)

While not FDA approved, clinical trial data (IPERGAY and Prevenir open-label Paris study) demonstrate efficacy of 86 percent or more for this event-driven dosing of F/TDF in men who have sex with men (MSM). For MSM who have sex less than once per week and can anticipate or delay sex to permit the initial dose to be at least 2 hours before sex, prescribing 2-1-1 F/TDF may be a viable option. For MSM with active hepatitis B infection, 2-1-1 is not an option, as intermittent dosing may cause hepatic flares. This off-label alternative dosing PrEP option for MSM is recommended by the International AIDS Society-USA. Off-label use may not be covered by insurance companies. In the trials, the MSM studied took, on average, 3–4 doses per week, which is known to be associated with high levels of protection in men. Less data is available on the efficacy of 2-1-1 in MSM having less frequent sex.

Only F/TDF is prescribed for 2-1-1 PrEP for MSM and is dosed as follows:

- 2 pills taken 2–24 hours before sex (closer to 24 hours is best)
- 1 pill taken 24 hours after the initial 2-pill dose
- 1 pill taken 48 hours after the initial 2-pill dose

Key educational points:

- If sex occurs the day after completing the 2-1-1 dosing, take 1 pill per day until 48 hours pass from the last sexual event.
- If sex occurs in a gap of fewer than 7 days from the last 2-1-1 dose, take 1 pill daily until 48 hours pass from the last sexual event.
- If sex occurs in a gap of greater than 7 days from the last 2-1-1 dose, restart 2-1-1 dosing.

Prescribing only 30 pills will allow dosing for up to 7 intermittent sexual events. Monitoring is the same as for daily PrEP.

Please see additional information on 2-1-1 PrEP in the Frequently Asked Questions section on page 16.

Required Laboratory Tests for Initial PrEP Services, Oral PrEP:

- Point-of-care (POC) HIV test immediately before PrEP initiation and HIV-1/2 antigen/antibody blood-based test for oral PrEP within 1 week of PrEP initiation. (The Centers for Disease Control and Prevention [CDC] recommends also drawing an HIV-1 polymerase chain reaction [PCR] viral load [can be same day].)
- Serum creatinine to calculate creatinine clearance: Creatinine Clearance Multi-Calc or comprehensive metabolic panel estimated creatinine clearance.
- Hepatitis B (HBV) surface antigen (HBsAg), hepatitis B surface antibody (HBsAb).

- Chlamydia/N. gonorrhoeae–nucleic acid amplification testing (NAAT)—perform site-specific swabs as indicated (oral, anal, vaginal) plus urine NAAT for men (and for women if vaginal swab not obtained).
- Rapid plasma reagin (RPR) titer for syphilis.
- Lipid panel if prescribed F/TAF.
- Hepatitis C virus (HCV) antibody for MSM, transgender women (TGW) and people who inject drugs (PWID).
- Pregnancy test (if indicated).

Laboratory Tests for Continued PrEP Services, Oral PrEP

Please see page 22 for full oral PrEP initiation and follow-up testing information.

INJECTABLE MEDICATION FOR PrEP

Cabotegravir extended-release injectable suspension (Apretude) 600 mg is administered as 2 initiation injections:

- A 3 mL intramuscular injection in the gluteal muscle on initial dose
- A second dose 4 weeks after the first dose (month 1 follow-up visit)

And then given every 8 weeks thereafter (month 3, 5, 7…etc., for follow-up visits).

Patients can either start their treatment with injectable cabotegravir or, if they are especially worried about side effects, may take oral cabotegravir (Vocabria) for 4 weeks to assess how well they tolerate the drug and relieve their anxiety.

Cabotegravir is not approved for self-injection or at-home administration. This medication must be administered at a medical provider's office or clinic. The injection is delivered using the Z-track method for deep intramuscular injection.

Injectable cabotegravir for PrEP has not been studied in men or women <18 years of age. These studies are underway, but until safety is determined for this population and reviewed by the FDA, cabotegravir is not recommended for adolescents.

Injectable cabotegravir has not been studied during pregnancy. Discuss pregnancy planning and assess adequacy of birth control before initiating cabotegravir.

For insured patients, as well as for those obtaining cabotegravir from patient assistance programs, note that it takes time to get the medication approved and then to receive it at the clinical site for injection. Consideration should be given for initiating same-day therapy using F/TDF or F/TAF while awaiting baseline cabotegravir lab results and medication arrival. Patients should understand that upon discontinuation of injectable cabotegravir, coverage of the tail period is recommended with oral PrEP therapy. Initiating PrEP with the oral drug provides them an opportunity to assess tolerance and provides protection while awaiting access.

Storage and Administration of Injectable PrEP:

- Cabotegravir is a suspension that does not require reconstitution or dilution for injection.

- Upper outer quadrant of the gluteal muscle is the only site health care professionals should inject, using the Z-track method.
- A 2-inch needle is recommended for intramuscular injection for participants with a body-mass index (BMI) of 30 or greater, and a 1.5-inch needle is recommended for participants with a BMI of less than 30.
- Store at 36º F to 77º F (exposure up to 86º F acceptable, per package insert) in original carton. Refrigeration is not required. Do not freeze. If refrigerated at the site, bring to room temperature before injection.
- Shake the vial vigorously before injecting. Suspension may remain in syringe for up to 2 hours. Filled syringe should not be placed in refrigerator and must be discarded if not used in 2 hours.

Contraindications to Injectable PrEP:

- HIV-positive status.
- Inability or unwillingness to come to clinic for cabotegravir injections on schedule.
- Signs/symptoms of acute HIV infection with history of recent at-risk exposure.
- Allergy or contraindication to any medicine in the PrEP regimen.
- Actively pursuing pregnancy.

Drug Interactions with Injectable PrEP

Cabotegravir is metabolized by UGT1A1 with some contribution from UGT1A9; strong inducers decrease cabotegravir levels and are contraindicated.

Contraindicated medications:

- Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Antimycobacterial: rifampin, rifapentine

Precautions:

- Rifabutin
    - If started before or at same time as cabotegravir, dose cabotegravir at 600 mg initially and 600 mg 2 weeks later, followed by 600 mg monthly cabotegravir injections while on rifabutin.
    - If started at the time of the second cabotegravir injection or later, dose cabotegravir as 600 mg monthly injections.
    - When rifabutin is stopped, resume cabotegravir 600 mg every 2 months.
- Methadone does not impact dose or schedule for cabotegravir, but methadone levels may decline, requiring dose adjustment of methadone.

Key Effectiveness Messages for Injectable PrEP:

- PrEP is highly effective for preventing HIV infection when adhering to the injection schedule.
- PrEP does not prevent pregnancy or STIs.

Side Effects

Cabotegravir side effects include pain and tenderness or hardness of the skin at the site of injection, which may last a few days and usually only occurs with the first 2 or 3 injections and then goes away. Patients should be informed that these reactions are common and transient. In addition, patients should be provided with proactive management advice:

- For the first 2–3 injections, take an over-the-counter pain medication a couple of hours before or soon after the injection and continue as needed for 1–2 days after the injection.
- Apply a warm compress or heating pad to the injection site for 15–20 minutes after the injection (i.e., after arriving back at home).

Required Laboratory Tests for Initial PrEP Services, Injectable PrEP:

- POC rapid combined antigen/antibody assay and HIV PCR RNA quantitative viral load drawn same day or obtained within a week of initial PrEP injection.
- Chlamydia/N. gonorrhoeae—NAAT— perform site-specific swabs as indicated (oral, anal, vaginal) plus urine NAAT for men (and women if vaginal swab not obtained).
- RPR titer for syphilis.
- Pregnancy test (if indicated).
- HCV antibody for MSM, TGW and PWID.

Discontinuing or Restarting Injectable PrEP

Patients without HIV on follow-up visit who wish to discontinue injections for PrEP or those who are a month or more late for an injection should be counseled about how to safely discontinue or restart cabotegravir injections for PrEP. There is a risk of developing drug-resistant HIV during the period of waning drug levels (the “tail period”). The tail period lasts for prolonged periods of up to 12 months or longer after last injection. This lengthy tail allows cabotegravir levels to fall below the protective threshold and remain at non-protective levels for some time after injections are discontinued. Incomplete treatment with low levels of cabotegravir could lead to acquisition of HIV and to mutations that confer resistance to integrase strand transfer inhibitors, thus complicating future treatment options. Patients need to understand the importance of taking daily oral PrEP within 8 weeks after their last injection or using other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated.

For planned missed injections:

If an individual plans to miss a scheduled (every-2-month) continuation injection visit by more than 7 days, they can take daily oral cabotegravir for a duration of up to 2 months to replace 1 missed scheduled (every-2-month) injection. The recommended oral daily dose is 1 30-mg tablet of oral cabotegravir. The first dose of oral PrEP should be taken approximately 2 months after the last injection dose of cabotegravir. Restart injection with cabotegravir on the day oral dosing completes or within 3 days. For oral PrEP durations greater than 2 months, an alternative oral regimen is recommended.

For unplanned missed injections:

If a scheduled injection visit is missed or delayed by more than 7 days and oral dosing has not been taken in the interim, clinically reassess the individual to determine if resumption of injection dosing remains appropriate.

Dosing after missed injections:

- Missed initial second injection after the first
  - If less than or equal to 2 months have passed, give 600 mg gluteal injection and schedule every-2-month injections.
  - If more than 60 days have passed, restart with 600 mg gluteal injection followed by second 600 mg gluteal injection 30 days later and then schedule every-2-month injections.
- Missed third or subsequent doses
  - If ≤90 days have passed, give 600 mg gluteal injection and resume every-2-month injections.
  - If more than 90 days have passed, restart with 600 mg gluteal injection followed by second 600 mg gluteal injection 30 days later and then schedule every-2-month injections.

Laboratory Tests for Continued PrEP Services, Injectable Medication

Please see page 26 for full injectable PrEP initiation and follow-up testing information.

CODING FOR PrEP VISITS:

- PrEP Initial/Counseling 5701
- PrEP Initiation/PrEP Rx 5702
- PrEP Follow-Up/Rx Refill 5703
- For further coding information: Department of Health Service and Time 2020-2021.pdf

SPECIAL SITUATIONS:

- For a high-risk potential exposure to HIV in the past 72 hours, use nPEP for 28 days, then, if clinically indicated, start PrEP.
- For a high-risk potential exposure in the past 15 days, monitor more closely at PrEP onset for signs and symptoms of acute HIV infection.
- For acute viral syndrome at presentation with history of high-risk exposure, draw HIV-1 PCR viral load and consider delaying PrEP start until result is known.
- F/TDF is preferred for women planning pregnancy. There is no data on injectable cabotegravir in pregnancy.
- Pregnancy while on PrEP (oral or injection) may continue if the benefits outweigh the risks. Adequate studies on breastfeeding are not available, and decision should be based on risk-benefit analysis.
- If HBsAb negative, offer vaccination; if HBsAg positive, educate on the risk of severe flares of hepatitis if PrEP is stopped and refer to primary care provider for ongoing evaluations of chronic HBV.
- PrEP is indicated for adolescents (younger than 18 years of age) who's sexual or injection behaviors put them at risk for acquiring HIV. Adolescents may not be provided PrEP in our county health department (CHD) programs unless parental consent is obtained. Refer adolescents to community providers for PrEP initiation.

EVALUATING AMBIGUOUS HIV TEST RESULTS

PrEP use alters the body's immune response to HIV should it escape the preventive antiretroviral therapy and result in infection. Practitioners need to remain vigilant for symptoms of acute HIV infection, which may or may not present in a person who acquires HIV while on PrEP medications. Ambiguous HIV testing results have been reported, for example:

- Positive POC antibody results but negative antigen results.
- Reactive qualitative NAT but "not detected" quantitative NAT

When faced with ambiguous HIV testing results:

- Re-address medication adherence since the last HIV test.
- Re-assess risks for HIV acquisition within 3–4 weeks before the lab draw.
- Send new specimens to the lab after a few days for antigen/antibody combination assay and quantitative HIV viral load.

If results are still ambiguous, contact the PrEP line (855-448-7737) for further testing advice and identification of a laboratory that can do specialized testing (the State Lab is able to process specimens to evaluate ambiguous test results).

While HIV status is being investigated, shared decision-making between practitioner and patient should include the following options:

- Continue PrEP regimen
    - The high effectiveness of PrEP increases the probability that adherent patients have not acquired HIV.
    - Continuing PrEP offers dual antiretroviral therapy and some viral suppression.
    - Even though resistance may develop (most commonly M184V), other highly effective antiretroviral therapies will be available for treatment.
- Add a third drug providing an nPEP regimen
    - The additional drug will most likely provide a fully suppressive treatment regimen but may make it difficult to obtain confirmation of the HIV diagnosis.
    - Adding the third drug may pose challenges in stopping the medication if it is determined the patient has not acquired HIV.
    - If acquisition of HIV is proven, the early antiretroviral therapy may be continued.
    - This is the best recommendation when patients report nonadherence to daily PrEP.
- For cabotegravir recipients for PrEP
    - Practitioners should not administer a new cabotegravir injection, as during the 1–2 weeks of additional testing, cabotegravir levels are likely remaining protective.
    - If acquisition of HIV is proven, begin immediate antiretroviral therapy.
    - If the patient has not acquired HIV, resume cabotegravir injections on schedule.

SAMPLES FOR PrEP:

As a potential cost-savings measure for the Department, we ask that CHD practitioners consider the use of manufacturer samples and vouchers for PrEP clients, as appropriate, and in accordance with the Bureau of Public Health Pharmacy's Policy DOHP 395-1, which states CHD practitioners are allowed to obtain manufacturer samples.

Ready, Set, PrEP is a nationwide program lead by the U.S. Department of Health and Human Services (HHS) that provides access to PrEP medication for patients who lack prescription drug coverage. Information is available at readysetprep.hiv.gov or 855-447-8410.

Gilead's Advancing Access program provides various coverage options for both insured and uninsured patients. Information is available at gileadadvancingaccess.com or 800-226-2056.

CHD practitioners can use our online pharmaceutical samples contact sheet to obtain the contact information for the appropriate representative for your area to access sample medications. Please note that this resource is for CHD clinicians and staff only.

FREQUENTLY ASKED QUESTIONS

Basic Prescribing Information

Q: How do I ensure the patient isn't at risk for being in the window period for HIV seroconversion when they are considering starting PrEP?

A: Obtain a detailed sexual/injection drug use risk assessment. If the patient's history of last at-risk exposure was greater than 15–21 days ago, an HIV 1/2 antigen/antibody blood-based HIV test should be adequate in ruling out recent HIV infection in most cases. If there is a high-risk exposure within the past 72 hours, the patient should be evaluated for nPEP. If there has been a high-risk exposure greater than 72 hours but less than 15–21 days ago, the clinician may want the patient to return for HIV testing appropriate to their risk history and the clinician's professional assessment. Starting PrEP and monitoring closely for signs and symptoms of HIV seroconversion is an acceptable option in some patients.

Q: What are signs and symptoms of acute HIV infection?

A: Within 2–4 weeks after infection with HIV, approximately 70 percent of people will have a flu-like illness. This is the body's natural response to HIV infection. The symptoms may last for a few days and up to several weeks. Around 30 percent of people with acute HIV infection will **NOT** have any symptoms during the acute phase of HIV infection.

Clinical Signs and Symptoms of Acute (Primary) HIV Infection (from 2021 CDC PrEP Guidance)

Features	Overall (n = 375) %	Sex		Route of transmission	
		Male (n = 355) %	Female (n = 23) %	Sexual (n = 324) %	Injection Drug Use (n = 34) %
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

Clinicians should suspect acute HIV infection in persons who report having engaged in exposure-prone behaviors in the 4 weeks prior to evaluation for PrEP (e.g., a condom breaking during sex with an HIV-positive partner, relapse to injection drug use with shared injection equipment). For all PrEP candidates with a negative or an indeterminate result on an HIV antigen/antibody test, and those reporting a recent possible HIV exposure event, clinicians should next solicit a history of nonspecific signs or symptoms of viral infection during the preceding month or on the day of evaluation.

Q: What if my patient experiences HIV seroconversion while on PrEP?

A: During PrEP treatment, anytime a patient has a positive HIV test result, it is urgent to notify and move the patient into HIV medical care. Less experienced clinicians are urged to seek consultation with an experienced HIV clinician. Consider consultation with the HIV Section Telehealth Team to assist with rapid access to HIV assessment, care and treatment.

Q: PrEP patients are tested for HIV as recommended for oral and injectable options. Do we need to perform pre- and post-test counseling at initial and follow-up visits?

A: While it is not required to perform pre- and post-test counseling at initial and follow-up visits, the opportunity for pre- and post-test counseling must be made available to all clients at all visits where an HIV test is performed. Per section 381.004(4), Florida Statutes, CHDs must provide the opportunity for pre- and post-test counseling, including the meaning of the test and test results, the potential need for confirmatory testing and the availability of partner notification services. Notification of patients related to offering pre- and post-test counseling can be managed through signage. CHDs may acquire the signs through the HIV Section's Testing and Counseling page.

Q: What if my patient presents for PrEP and asks for injectable cabotegravir?
A: There are two options for insured patients' access to injectable cabotegravir. Insurance companies may designate the medication as a pharmacy benefit or medical benefit. If designated a pharmacy benefit, the ViiV Connect Portal can aid in securing insurance access to the drug. If designated a medical benefit, the physician office must purchase the medication and then bill the insurance for the cost of the drug and the patient for the copay, if any is due. If there is no payment source, the CHD will have to request injectable cabotegravir through the patient assistance program. Patients need to know that access to injectable cabotegravir is not immediate, as the drug is procured and shipped to the clinical site for administration at a later date.

Patients presenting for PrEP are at risk of acquiring HIV. Please consider initiating PrEP with an oral option while awaiting receipt of injectable cabotegravir.

Q: What if my PrEP patient has clinical complaints or lab abnormalities that are unrelated to their PrEP therapy?
A: Every PrEP patient needs to be informed we are providing PrEP clinical services for the prevention of HIV infection. Each patient should be informed repeatedly of the need to obtain a primary care provider and should be assisted with options for care in your region. Once the patient has an identified primary care practitioner, obtain consent to share the labs and medical visit information with their provider.

Q: What if my PrEP patient results a positive hepatitis C, HCV antibody?
A: If your site uses Quest lab and has a positive HCV antibody result, you will receive the results of the HCV viral load, as Quest requires it to be bundled reflexively when ordering the HCV antibody test. Labcorp allows sites to order just an HCV antibody test, which lessens cost. A positive result on the HCV antibody test would require further diagnostic workup by the patient's primary care provider to include an HCV viral load.

Adolescents and Other Special Populations (Pregnant Persons, Transgender Women)

Q: Can an adolescent take PrEP?
A: The FDA has approved the use of either oral F/TAF (excluding for those at risk from receptive vaginal sex) or F/TDF and injectable cabotegravir for at-risk adults and adolescents weighing at least 35 kilograms (77 pounds) not currently diagnosed with HIV. Consider PrEP for sexually active adolescents at risk for HIV and refer to a local provider for PrEP assessment unless parental consent can be obtained.

Q: Can PrEP be prescribed to people who are pregnant or planning pregnancy?
A: PrEP may be one option to help protect someone who is HIV seronegative from acquiring HIV in serodifferent couples or for people at risk of HIV acquisition during attempts to conceive or during pregnancy.

- Consultation is available at the National Clinician Consultation Center on Perinatal HIV/AIDS at National Clinician Consultation Center or 888-448-8765, 24 hours a day, 7 days a week.

- If a patient is pregnant when starting F/TDF or becomes pregnant while on F/TDF, discuss the known risks and benefits of taking PrEP during pregnancy. (See AIDSmap's PrEP in pregnancy: safe, but many unanswered questions.)
- After discussing the potential risks of F/TDF, consideration can be given to continuing PrEP during and after pregnancy for those with ongoing risk for HIV. F/TDF is excreted in breast milk, and breastfeeding is not recommended; assess the risk/benefit of continuing PrEP therapy for those breastfeeding an infant.
- Injectable cabotegravir use has not been evaluated during pregnancy and should only be used or continued during pregnancy if the benefit outweighs the potential risk to the fetus.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry.

Q: Is F/TAF (F/TAF) being tested for use for PrEP in women?

A: The safety of F/TAF for PrEP in women will be evaluated with at least 2 studies, CONRAD 137 (active controlled study evaluating the safety and efficacy of F/TAF and F/TDF in 525 ciswomen) and PrEP VACC (2-stage HIV vaccine trial; in the first stage, women will be randomized 1:1 to receive either F/TAF or F/TDF for 26 weeks). Results are not available currently.

Q: Does estrogen therapy for TGW have any effect on Tenofovir and emtricitabine (FTC) levels or on cabotegravir?

A: Yes, there is a decrease in rectal tissue concentration of these drugs, but levels are consistent with at least 4 doses/week. Data suggest that TGW might need higher levels of adherence than cis men when on feminizing therapy.

There are no drug interactions between cabotegravir and hormonal therapy.

Bone Density and Renal Function

Q: Are there concerns for osteopenia/osteomalacia/osteoporosis?

A: There may be a risk of bone loss associated with F/TDF. Risk factors include being over age 50, female or menopausal, having a family history of osteopenia, low body weight, history of broken bones or loss of height, inadequate dietary intake of calcium and vitamin D, low intake of fruits and vegetables, too much dietary protein, too much dietary sodium and caffeine, inactive lifestyle and excessive alcohol intake, smoking, and losing weight.

Review Are You at Risk? National Osteoporosis Foundation. Discuss risk of bone loss with all PrEP patients. For individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia, consider closer monitoring.

Q: Is chronic kidney disease or the presence of risk factors (>65 years of age, black race, hypertension, diabetes or concomitant nephrotoxic drugs) a limitation for PrEP?

A: With individuals who have pre-existing risk factors, consider closer monitoring of creatinine and urine protein during long term oral PrEP therapy. You may also consider switching to

cabotegravir injections for PrEP, which can be used in patients with significant renal disease, for whom tenofovir-containing regimens are contraindicated.

Q: What if the estimated creatinine clearance (eCrCl) is declining?

A: If eCrCl is steadily declining but still greater than or equal to 60ml/min for F/TDF or 30 ml/min for F/TAF, assess for protein loading, protein powders, creatine supplements or regular or high-dose use of NSAIDs. Creatinine measurements vary from day to day and depend on hydration, exercise, diet creatine use (common among body builders) and other factors. If a single creatinine measurement is above the normal range, the measurement should be repeated. Calculation of estimated glomerular filtration rate (eGFR) is based on lean body weight.

- Female lean body weight calculator
- Male lean body weight calculator
- To manually calculate the eGFR: eGFR CrCl Cockroft-Gault

Note: For transgender persons not on hormonal therapy, use their gender assigned at birth. If they have been on hormone therapy for more than 3 months, use their current gender.

Options for continued therapy if experiencing a steady decline in creatinine clearance:

- If assigned male at birth and on F/TDF, switch to F/TAF or cabotegravir injections.
- For females on F/TDF, switch to cabotegravir injections.

Q: How do you check for drug interactions with F/TDF or F/TAF?

A: Obtain a thorough medication history, including over-the-counter medications. Drugs that may impair renal function (such as NSAIDs) may interact with F/TDF. Drugs that induce p-glycoprotein (such as carbamazepine, oxcarbazepine, phenytoin, rifabutin, rifampin) may interact with F/TAF. Use Liverpool HIV Interactions to check for interactions.

Hepatitis B Virus

Q: How do you determine if a patient has chronic active HBV infection?

A: **F/TDF** and **F/TAF** are active against HBV infection. F/TDF and F/TAF may be used as treatment for HBV infection and for prevention of HIV infection. See HHS's Recommendations Regarding Hepatitis B Virus/HIV Coinfection.

- Chronic active HBV infection is diagnosed when HBsAg is positive and there is presence of hepatitis B DNA quantitative viral load. When HBsAg results are positive, call the patient and obtain hepatitis B DNA viral load, hepatitis Be-Antigen and hepatitis Be-Antibody and assess for liver fibrosis using the Fibrosis-4 index. Refer to primary care for management.
- In patients with chronic active HBV infection, discontinuation of F/TDF and F/TAF requires close monitoring because of the concern for rebound viremia and a flare in hepatitis. Severe acute exacerbations of HBV have been reported in patients with HBV infection who have discontinued F/TDF and may occur with discontinuation of F/TAF.
- Patients need to be in the care of a primary care provider or liver specialist for ongoing monitoring of their HBV infection while receiving PrEP services. For those underinsured, please assist with access to a local federally qualified health center for HBV treatment.

Labs

Q: What do I do when faced with abnormal labs in our PrEP program?
A: Our role is to provide PrEP services per peer reviewed guidelines. If a lab abnormality occurs in what is deemed to be a critical lab result, it should be addressed by the practitioner providing the care. If the lab abnormality is one that requires follow up, the patient should be referred to their primary care provider.

Q: How do I code for PrEP labs?
A: Using the recently developed program component "02H," CHDs using the State Public Health Laboratories are now able to charge PrEP-related lab costs for HIV, hepatitis and STI testing to the HIV/AIDS Section for those unable to afford lab-related charges, as long as funding is available. Potential resources for local funding of PrEP labs include general revenue, 4BAPS and/or program-generated income. Please contact the Prevention Program manager at Mara.Michniewicz@flhealth.gov for further instruction.

Medication Adherence

Q: Can PrEP fail despite good adherence?
A: Yes, although cases of HIV seroconversion in persons known to be fully adherent to PrEP are rare, there have been reports of HIV seroconversion among persons with multidrug-resistant HIV as well in persons with wild-type HIV (HIV that does not have resistance to PrEP medication). F/TDF, F/TAF and injectable cabotegravir are single components of an HIV prevention program and rare cases such as these support the importance of condom use and continued motivational interviewing for behavior change.

Q: Is 2-1-1 PrEP an option for MSM?
A: This is a decision individually made between the practitioner and patient. Non-daily 2-1-1 oral PrEP is a dosing approach for F/TDF that has been studied in MSM in France and Canada. This approach is being used in some clinics in Europe, Canada and now in the United States. This non-daily dosing may be appropriate for MSM. Currently, the only FDA-approved dosing strategy for oral PrEP in the United States is the once-daily dosing of F/TDF or F/TAF. The CDC continues to recommend **daily use** of oral PrEP, as approved by the FDA.

In the IPERGAY and Prevenir studies, 2-1-1 PrEP was found to be protective for the insertive and receptive partner during anal sex. Non-daily PrEP has not been studied in cis women, cis men who have sex with women, trans men, trans women or PWID. Current research suggests that non-daily F/TDF is not likely to reach or remain at high enough levels in the cervix or vagina to provide effective protection against HIV infection. In the IPERGAY and Prevenir studies, 2-1-1 PrEP was found to be protective for the insertive and receptive partner during anal sex.

The 2-1-1 PrEP dosing strategy was studied in MSM as an alternative to daily dosing for persons who are at ongoing risk of HIV infection through anal sex and prefer not to take daily PrEP despite counseling about safety and tolerability of daily PrEP and:

- Anticipate being able to plan their sexual intercourse.

- Will take their pre-sex dose of 2 F/TDF tablets at least two hours (and preferably closer to 24 hours) before sexual activity or delay sexual activity for at least 2 hours (and preferably 24 hours) after taking their pre-sex dose of 2 F/TDF tablets.
- Can take daily doses of F/TDF for 48 hours after their last sexual intercourse.
- Do NOT have chronic active HBV infection.
- Have a calculated creatinine clearance greater than 50 mL/min.

Study participants took:

- Two F/TDF tablets 2–24 hours before sex (closer to 24 hours before sex was preferred).
- One F/TDF pill 24 hours after the first 2 pills.
- One F/TDF pill 24 hours after the second dose.

Hence the name "2-1-1." If they continued to have sex on multiple consecutive days, they continued taking 1 F/TDF per day until 48 hours after their last sexual contact.

Things to Note

- 2-1-1 PrEP has a similar toxicity and side effect profile to daily PrEP. Individuals should not choose 2-1-1 PrEP to decrease side effects or toxicity.
- Individuals opting to use 2-1-1 PrEP should ensure that **every** sexual episode is covered by condoms, PrEP or both. Using condoms in addition to these strategies reduces risk for other STIs (e.g., syphilis, gonorrhea and chlamydia).
- 2-1-1 dosing makes the most sense for people who have, on average, no more than 1 sexual encounter per week.
- People using 2-1-1 PrEP may find that they want to switch to daily PrEP if their frequency of sexual intercourse changes. Patients should not choose 2-1-1 PrEP simply due to cost without exploring how they can access daily PrEP.
- 2-1-1 PrEP should be prescribed by a practitioner. Acquiring PrEP for 2-1-1 from friends or sex partners puts people at risk of acquiring HIV as they are not taking PrEP as prescribed for them.
- Patients taking either daily PrEP or 2-1-1 PrEP should be tested for HIV and STIs at least every 3 months.

Comparison of Daily PrEP and 2-1-1 PrEP

	Daily PrEP	**2-1-1 PrEP**
Effective HIV prevention for?	Anyone	Only studied in cis men who have sex with cis men
What kind of sexual contact does it provide protection for?	Anal, vaginal, oral	Anal sex **only** (insertive and/or receptive)
Side effects?	As listed by provider	Same as daily PrEP
How is it taken?	One pill every day	A pre-sex dose of 2 tablets 2–24 hours before sex, then 1 pill every 24 hours after the pre-sex dose until 2 post-sex doses.

When are doses taken?	Any time, once a day	Must be timed at least 2 hours before sex and continued for multiple timed doses after sex—consider setting an alarm for a reminder.
Requires planning sex in advance?	No	Yes, by at least 2 hours and preferably by 24 hours.
What if a dose is missed?	Patient should take it as soon as they remember unless it is the next day. Do not double up on doses.	May need PEP instead and should contact provider.

Other STIs

Q: Is PrEP usage associated with an increased incidence of STIs?
A: Clinical studies have shown PrEP usage is associated, in some patients, with an increased incidence of STIs. In PrEP programs within our CHDs, we recommend routine STI screening at each visit regardless of symptoms. Finding and treating asymptomatic STIs reduces the risk of HIV acquisition and the risk of transmitting infections to others. Finding STIs is an opportunity for counseling and consideration of more frequent STI screening may be indicated.

Q: Should female patients be screened for trichomoniasis even if asymptomatic?
A: Although not a current recommendation in PrEP guidelines, *T. Vaginalis* infection increases the risk for HIV acquisition two- to threefold. Testing should be done in women reporting vaginal discharge. Screening should be considered in women reporting multiple sex partners or exchanging sex for payment or illicit drug use.

Transitioning Immediately from nPEP To PrEP

Q: How do you transition from nPEP to PrEP?
A: Transitioning from nPEP to PrEP without interruption at the completion of the 28-day nPEP course has the advantages of (1) maintaining satisfactory antiretroviral drug levels for PrEP (if nPEP adherence has been good) and (2) maximizing continuous prevention measures through continuity of nPEP to PrEP care.

Essential steps at conclusion of 28 days of nPEP:

- Repeat a rapid HIV test (ideally with a fourth-generation antigen/antibody assay) and assess for signs and symptoms of acute HIV infection.
- If the rapid HIV test is positive or suspicion exists of possible acute HIV infection, draw blood for confirmatory testing and continue a 3-drug nPEP regimen pending confirmation of HIV status.
- If HIV infection is confirmed, refer to the Florida Department of Health Test and Treat Guidance.

If the rapid HIV test is negative and no signs or symptoms of acute infection exist, replace the nPEP regimen with one of the following for PrEP:

- F/TDF daily pill
- F/TAF daily pill (for those exclusively having anal sex)
- Cabotegravir bimonthly injection

Complete any PrEP baseline laboratory testing not already performed as part of nPEP testing and:

- Provide medication adherence and risk-reduction support counseling.
- Complete any insurance/medication assistance paperwork required to cover PrEP medications (might be different than nPEP medications).
- Schedule follow-up visits for HIV, STI and other laboratory testing, as well as medication refills, based on standard PrEP clinical practice guideline recommendations.

Primary Care Considerations

Q: Is primary care provided for PrEP patients?

A: Provision of PrEP affords the opportunity to manage other preventive health measures during both initial and follow-up visits, especially for persons who may not otherwise be engaged in primary care. These health measures include vaccinations, screening for sex-specific conditions and screening for mental health, tobacco/nicotine use and alcohol-use disorder. When providing sex-specific health care for transgender persons, the principle of “screen what you have” regarding specific body parts (prostate, cervix, etc.) should be applied. Please see the table on the following page for more information.

	MSM[1]	MSW[2]	Women	PWID[3]
Vaccines[4] (If not previously vaccinated)				
Hepatitis A	Yes	Yes	Yes	Yes
Hepatitis B	Yes	Yes	Yes	Yes
Human papillomavirus	Through age 26	Through age 26	Through age 26	Through age 26
Meningococcal B (best ages to obtain vaccine are listed)	Ages 16–18	Ages 16–18	Ages 16–18	Ages 16–18
Influenza	Yes	Yes	Yes	Yes
General Health				
Screen for Hepatitis C infection[5]	Ages 18–79	Ages 18–79	Ages 18–79	Ages 18–79
Screen for depression	Yes	Yes	Yes	Yes
Screen for unhealthy alcohol use	Ages 18 and older	Ages 18 and older	Ages 18 and older	Ages 18 and older
Screen for smoking	Yes	Yes	Yes	Yes
Screen for intimate partner violence	Yes	Yes	Yes	Yes
Women's Health				
Mammography[6]			Ages 50–74, every 2 years	If female, ages 50–74, every 2 years
Screen for cervical cancer[6,7]			Ages 21–65, every 3 years	If female, ages 21–65, every 3 years
Men's Health				
Screen for prostate cancer[6]	Ages 55–69	Ages 55–69		If male, ages 55–69

[1] Men who have sex with men.
[2] Men who have sex with women.
[3] Persons who inject drugs.
[4] Per Advisory Committee on Immunization Practices recommendations, for adults ages 27 through 45 years. Clinicians can consider discussing human papillomavirus vaccination with people who are most likely to benefit.
[5] Per United States Preventative Services Task Force recommendations.
[6] Apply the "screen what you have" principle for transgender persons.
[7] Per ASCCP American Society of Colposcopy and Cervical Pathology guidelines.

ADDITIONAL GUIDANCE:

- PrEP Chapter of CDC's *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention*
- National Clinician Consultation Center PrEP page
- AIDS Institute Clinical Guidelines
- Clinical Guidelines Program PrEP to prevent HIV and promote sexual health
- Clinical Consultation Center at University of California, San Francisco: 855-HIV-PrEP (855-448-7737)
- North Florida AIDS Education and Training Center for antiretroviral patient medication information sheets.
- HealthHIV Tips and Tricks for Covering Costs of PrEP
  Pre-Exposure Prophylaxis Service (PrEP line): 855-HIV-PrEP (855-448-7737)

TELEHEALTH

Telehealth services for PrEP are available. When anticipating a telehealth PrEP patient, please call one of the following staff members, starting with the first person on the list and progressing downward:

- Telehealth APRN—239-339-3899
- Telehealth PA—904-254-0258
- Adminitrative Assistant—239-292-3054
- HIV/AIDS Section Statewide Practitioner—850-519-3734

One of the staff members noted above will accept the telehealth session and will be the one with whom you establish an audiovisual (AV) connection. Before each telehealth encounter, test the AV system and troubleshoot any connection issues.

LABORATORY GUIDANCE FOR ORAL MEDICATION

TEST	Screening/ Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP	Quest	LabCorp	State Lab
HIV POC HIV antibody rapid test with lab Ag/Ab combination assay sent with reflex to HIV PCR RNA viral load	X*	X			X*	HIV-1/-2 Ag/Ab, with reflex to differentiate HIV-1 from HIV-2 and, if antibody neg (acute HIV), reflexes to HIV-1 RNA at additional charge (91431, CPT 87389) HIV-1 RNA Quantitative Real Time PCR (40085, CPT 87536)	HIV p24 antigen/antibody with reflex to confirmation (083935, CPT 87389) HIV p24 antigen/antibody with reflex to HIV-1/HIV-2 antibody differentiation assay reflex to HIV-1/HIV-2 RNA qualitative NAA (83935, CPT 87389)	HIV-1/-2 Ag/Ab (0500) HIV PCR RNA viral load (87536)
Creatinine (to calculate eGFR) – link to calculator below	X		Twice yearly If age ≥50 and eCrCl <90 mL/min on PrEP initiation	Once yearly if age < 50 and eCrCl ≥90 mL/min on PrEP initiation	X	Creatinine (0000375, CPT 82565)	Creatinine (003004, CPT 82575)	Not available
Syphilis	X	MSM/TGW	X		MSM/TGW	RPR w/reflex to titer (at additional cost) (92156, CPT 86592)	RPR qualitative to RPR titer and treponemal pallidum-specific test on reactive at an additional fee (12005, CPT 86592)	RPR w/reflex to titer (0250)

				[redacted]		Syphilis antibody with cascading reflex (90349, CPT 86780)	Syphilis screening cascade treponema-specific test can be positive in all stages of syphilis (pinta and yaws). When positive, reflexes to qualitative RPR, and if positive, reflexes to an RPR titer. If RPR is negative, reflexes to a second treponemal test for confirmation. (82345, CPT 86780)	
Chlamydia/ gonorrhea	X	MSM/TGW	X		MSM/TGW	C/G RNA, TMA (CPT 87591) rectal (16506) throat (70051) urine (36341) urogenital/vaginal (11363) Patient should not have urinated within 1 hour prior to collection. Female patients should not cleanse the labial area prior to providing the specimen.	Chlamydia/ N. gonorrhoeae NAA (CPT 87591) rectal (188672) pharyngeal (188698) urine (183914) vaginal (183160) First-void urine (patient should not have urinated for 1 hour prior to specimen collection). N. gonorrhoeae test only (188086, CPT 87591)	CT/GC (0430)

						Preferred specimen is vaginal swab.		
Hepatitis B surface antigen and surface antibody	X					Hep B Surface Antigen w/Reflex (498, CPT 87340) Hep B Surface Antibody, Qual (499, CPT 86706)	Hep B Surface Antigen (HBsAg) Screen, Qual (006510, CPT 87340) Hepatitis B Surface Antibody, Qual (006395, CPT 86706)	Hepatitis BsAg (0300) Hepatitis BsAb (0310)
Hepatitis C serology	MSM, TGW and PWID only			MSM, TGW and PWID only		HEP C AB W/reflex to quantitative real time PCR (08472, CPT 86803)	Hepatitis C Virus (HCV) Antibody (140659, CPT 86803)	Hep C antibody screening (0330)
Lipid panel (for F/TAF only)	X			X		Lipid Panel, Standard (Cholesterol Total, Triglycerides, HDL Cholesterol, LDL-Cholesterol, [calculated], Cholesterol/HDL Ratio [calculated], Non-HDL Cholesterol [calculated]) (7600, CPT 80061)	Lipid Panel (235010, CPT 80061)	Not available

Pregnancy (usually CHD POC test)	Persons with childbearing potential	Persons with childbearing potential	[redacted]		Persons with childbearing potential	HCG, total qualitative serum pregnancy test (008435, CPT 84703)	Human Chorionic Gonadotropin (hCG), β-Subunit, Quantitative Serum (004416, CPT 84702)	Not available

***Assess for acute HIV infection**

Sources:

- Quest Diagnostics: Test Directory
- Labcorp: Search Our Health Care Diagnostics Tests Menu
- National HIV Curriculum: Glomerular Filtration Rate (GFR) Estimate by MDRD 4-Variable Equation – Clinical Calculators

LABORATORY GUIDANCE FOR INJECTABLE MEDICATION

TEST	Initiation Visit and Q 12 months	Q 1 month	Q 2 months	Q 4 months	Q 6 months	When stopping therapy	Quest	LabCorp	State Lab
HIV Rapid POC Ag/Ab assay[1] plus HIV PCR RNA viral load - preferred **Or** Lab-based Ag/Ab combination assay plus HIV PCR RNA viral load with results prior to first injection	X	X	X	X	X	X	HIV-1/-2 Ag/Ab, with reflex to differentiate HIV-1 from HIV-2 and, if antibody neg (acute HIV), reflexes to HIV-1 RNA at additional charge (91431, CPT 87389) HIV-1 RNA Quantitative Real Time PCR (40085, CPT 87536)	HIV p24 antigen/antibody with reflex to confirmation (083935, CPT 87389) HIV p24 antigen/antibody with reflex to HIV-1/HIV-2 antibody differentiation assay reflex to HIV-1/HIV-2 RNA qualitative NAA (083935, CPT 87389)	HIV-1/-2 Ag/Ab (0500) HIV PCR RNA viral load (87536)
Syphilis	X	[redacted]		MSM/TGW only	Heterosexually active women and men only	MSM/TGW only	RPR w/reflex to titer (at additional cost) (92156, CPT 86592) Syphilis antibody with cascading reflex	RPR qualitative to RPR titer and treponemal pallidum-specific test on reactive at an additional fee (12005, CPT 86592) Syphilis screening cascade treponema- specific test can be positive in all stages of syphilis (pinta and yaws). When positive,	RPR w/reflex to titer (0250)

		[redacted]				(90349, CPT 86780)	reflexes to qualitative RPR, and if positive, reflexes to an RPR titer. If RPR is negative, reflexes to a second treponemal test for confirmation. (82345, CPT 86780)	
Chlamydia/ Gonorrhea	X		MSM/TGW only	Heterosexually active women and men only	MSM/TGW only	C/G RNA, TMA (CPT 87591) rectal (16506) throat (70051) urine (36341) urogenital/vaginal (11363) Patient should not have urinated within 1 hour prior to collection. Female patients should not cleanse the labial area prior to providing the specimen. **Preferred specimen is vaginal swab**	Chlamydia/ N. gonorrhoeae NAA (CPT 87591) rectal (188672) pharyngeal (188698) urine (183914) vaginal (183160) First-void urine (patient should not have urinated for 1 hour prior to specimen collection) N. gonorrhoeae test only (188086, CPT 87591)	CT/GC (0430)
Hepatitis C serology	MSM, TGW and PWID only					HCV Ab w/reflex to quant real time PCR (only option to order HCV with Quest)	HCV Ab (with Labcorp, you can get the antibody only) (140659, CPT 86803)	

		[redacted]				(0008472, CPT 86803)		
Pregnancy (usually CHD POC test)	Persons with childbearing potential	Persons with childbearing potential	Persons with childbearing potential	[redacted]	Persons with childbearing potential	HCG, total qualitative serum pregnancy test (008435, CPT 84703)	Human Chorionic Gonadotropin (hCG), β-Subunit, Quantitative Serum (004416, CPT 84702)	

Sources:

- Quest Diagnostics: Test Directory
- Labcorp: Search Our Health Care Diagnostics Tests Menu

PATIENT ASSISTANCE PROGRAMS

Manufacturer	Drug name	Link
Gilead	Truvada (F/TDF)	NeedyMeds Truvada
Gilead	Descovy (F/TAF)	NeedyMeds Descovy
ViiV	Apretude (cabotegravir)	Apretude Enrollment Form