

PrEP Clinical Guidelines

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FLORIDA DEPARTMENT OF HEALTH

May 2020



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At A Glance PrEP Initiation Overview for County Health Departments
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One goal of the Florida Department of Health is to reduce the number of new diagnoses of HIV in the state of Florida. Biomedical interventions are now available which allow an individual to take a medication daily which will significantly reduce the risk of acquiring HIV. This biomedical intervention 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 7 days, or with a negative rapid HIV test at time of PrEP initiation, with a blood based confirmatory test to be drawn at the same time.

PrEP is indicated for the following HIV negative individuals:

- Persons with a sexual partner living with HIV who is not consistently virally suppressed, or
- Person who injects drugs **or**
- Sexually active persons not in a monogamous relationship with someone known HIV negative

AND with any of the following:

- Vaginal or anal sexual intercourse without condoms, or
- A sexual partner with one or more HIV risk factors, or
- A history of a sexually transmitted infection (STI) by lab testing or self-report or syndromic STI treatment, or
- A person deemed at risk of HIV acquisition at the end of non-occupational post-exposure prophylaxis (nPEP) therapy, or
- sharing needles or works or
- A patient requesting PrEP

Contraindications:

- HIV-positive status
- Estimated creatinine clearance less than 60 mL/min for Truvada®
- Estimated creatinine clearance less than 30 mL/min or women using vagina for sex for Descovy®
- Signs/symptoms of acute HIV infection with history of recent at-risk exposure
- Allergy or contraindication to any medicine in the PrEP regimen
- Individuals that are unwilling to take a pill every day or follow-up every three months for lab work

Key effectiveness messages:

- PrEP is highly effective for preventing HIV infection when taken every day as prescribed
- PrEP does not prevent pregnancy or STIs

Side-effects:

- PrEP users may have side-effects such as nausea, abdominal cramps, headache; these are usually mild and resolve over the first few weeks of taking PrEP.
- New onset or worsening renal function is possible with Truvada® for PrEP use.
- One percent average loss of bone mineral density; recovers after discontinuing Truvada® for PrEP use.

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Required Laboratory Tests for Initial PrEP Services:

- HIV 1/2 Antigen/Antibody 4th generation blood-based test plus/minus 3rd/4th generation rapid HIV test.
- Comprehensive Metabolic Panel or serum creatinine to calculate creatinine clearance. See link to calculate creatinine clearance: <https://globalrph.com/medcalcs/creatinine-clearance-multi-calc/>
- Hepatitis panel (chronic) or, at a minimum, hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb).
- Chlamydia/N. gonorrhoea – Nucleic-Acid Amplification Testing (NAAT)- perform site specific swabs as indicated (oral, anal, vaginal) plus urine NAAT for men (not needed for women if vaginal swab obtained).
- Rapid Plasma Reagin (RPR titer) for syphilis.
- Urinalysis or urine dipstick to check for protein.
- Pregnancy test (if indicated).
- Optional: vaginal swab for T. Vaginalis NAAT

Laboratory Tests for Continued PrEP Services:

Please see page 8 for full PrEP initiation and follow-up testing information.

Special situations:

- High-risk potential exposure to HIV in the past 72 hours: use non-occupational post-exposure prophylaxis (nPEP) for 28 days, then if clinically indicated start PrEP.
- High risk potential exposure in the past 15 days, monitor more closely at PrEP onset for signs and symptoms of acute HIV infection.
- Acute viral syndrome at presentation, draw HIV-1 Polymerase Chain Reaction (PCR) viral load and consider delay in PrEP start until result known.
- Pregnancy: PrEP can be offered and/or continued but breast feeding is not recommended.
- If Hepatitis B Surface Antibody negative offer vaccination; if HBsAg positive educate on risk of severe flares of hepatitis if PrEP stopped and refer to Primary Care Provider for ongoing evaluations of chronic Hepatitis B infection.
- Adolescents (younger than 18 years of age) may not be provided PrEP in our CHD programs unless parental consent obtained. Refer adolescents to community provider for PrEP initiation.

Medications for PrEP:

Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) fixed dose combination (Truvada®) and tenofovir alafenamide (TAF)/emtricitabine (FTC) fixed dose combination (Descovy®) have been approved by the United States Food and Drug Administration (FDA) for use as PrEP in combination with safer sexual practices 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 compliant in taking PrEP medication every day.

Clinical trial data shows Descovy® for PrEP to be an effective HIV prevention strategy for men who have sex with men and transgender women during anal receptive and insertive sex. Descovy® is **NOT** indicated for use as PrEP in women having vaginal sex.

Frequently Asked Questions

Basic prescribing information and side effects

Q: Is the patient at risk for being in the window period for HIV seroconversion at the time you are considering starting PrEP?

A: Obtain a detailed sexual/IDU 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 4th generation 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 his/her 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 two to four 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. These symptoms can include fever, chills, night sweats, sore throat, muscle aches, fatigue, lymphadenopathy, and oral ulcers. The symptoms may last for a few days and up to several weeks. Around 30 percent with acute HIV infection will **NOT** have any symptoms during the acute phase of HIV infection.

Q: What if my patient experiences acute 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/AIDS Section Telehealth team to assist with rapid access to HIV assessment, care, and treatment.

Q: PrEP patients are tested for HIV every quarterly visit. 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 which includes the meaning of the test and test results, the potential need for confirmatory testing, and the availability of partner notification services.

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.

Adolescents and special populations (pregnancy, transgender)

Q: Can an adolescent take PrEP?

A: The FDA has approved the use of Truvada® in adults and adolescents weighing at least 35 kilograms (kg.) not currently diagnosed with HIV. Descovy® is indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the sexual risk of HIV-1 acquisition f,

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excluding individuals at risk from receptive vaginal sex. Consider PrEP for adolescents at high risk for HIV and refer to local provider for PrEP assessment unless parental consent obtained.

Q: Pregnancy or planning pregnancy?

A: PrEP may be one option to help protect the HIV seronegative partner from acquiring HIV infection in serodifferent couples during attempts to conceive.

- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking Truvada® during pregnancy.
- After discussing the potential risks of Truvada®, consideration can be given to continue PrEP during and after pregnancy for those with ongoing risk for HIV. Truvada® is excreted in breast milk; assess the risk/benefit of continuing PrEP therapy for a woman breastfeeding her infant. See information at:
www.cdc.gov/hiv/pdf/prep_gl_clinician_factsheet_pregnancy_english.pdf.
- Consultation is available at the National Clinician Consultation Center on Perinatal HIV/AIDS at nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/ or call (888) 448-8765, 24 hours, seven days a week.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry at www.apregistry.com.

Q: Is Descovy® (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 two studies, CONRAD 148 (active controlled study evaluating the safety and efficacy of F/TAF and F/TDF in 525 ciswomen) and PrEP VACC (two-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 on transgender women (TGW) have any effect on Tenofovir (TFV) and emtricitabine (FTC) levels?

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

Bone density

Q: Does the patient have osteopenia/osteomalacia/osteoporosis?

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

- Review <https://www.nof.org/preventing-fractures/general-facts/bone-basics/are-you-at-risk/>
- Discuss risk of bone loss with all PrEP patients. For individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia, consider closer monitoring.

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HBV

Q: Does the patient have chronic active HBV infection?

A: **Truvada®** and **Descovy®** are active against HBV infection.

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/25/hbv-hiv>

- Truvada® and Descovy® may be used as treatment for HBV infection and for prevention of HIV infection.
- Chronic active HBV infection is diagnosed when Hepatitis B surface antigen (HBsAg) is positive and there is presence of Hepatitis B DNA quantitative viral load. When HBsAg is resulted as positive, call the patient and obtain Hepatitis B bDNA viral load, Hepatitis Be-Antigen and Be-Antibody and FIB-4 and refer to primary care for management.
- In patients with chronic active HBV infection, discontinuation of Truvada® and Descovy® 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 infected with HBV who have discontinued Truvada® and may occur with discontinuation of Descovy®.
- 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 (FQHC) for HBV treatment.

Labs

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.

Medication access:

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. Use the Gilead Advancing Access Medication Assistance program (<https://www.gileadadvancingaccess.com/>) or Ready, Set, PrEP Program (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program>) to obtain PrEP medication for applicable patients in need. In cases where you are unable to locate resources to assist and provide ongoing PrEP therapy for a person in need, notify your local HIV/AIDS Program Coordinator (HAPC) or call HIV/AIDS Section Medical Unit.

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 amongst persons infected with multidrug resistant HIV and as well in persons with wild-type HIV (HIV that does not have resistance to Truvada®). Truvada® and Descovy® are one component of an HIV prevention program and rare cases such as these support the importance of condom use and continued motivational interviewing for behavior change.

Other STIs

Q: Is PrEP usage associated with an increased incidence of sexually transmitted infections (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 as well the risk of transmitting infections to others. Finding STIs in 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, exchanging sex for payment, or illicit drug use.

Renal

Q: What if the patient has a history of known renal insufficiency?

A: Assess estimated or calculated creatinine clearance at or before initiating treatment. In patients at risk for renal dysfunction, assess estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein before starting treatment and periodically during treatment. Creatinine Clearance Calculator: www.globalrph.com/crcl.htm. Practitioners must weigh the risk of HIV infection versus potential for worsening renal function. Contact the Clinician Consultation Center <https://nccc.ucsf.edu/>.

Q: Is the patient at risk for chronic kidney disease? (>65 years of age, black race, hypertension, diabetes or concomitant nephrotoxic drugs)?

A: Discuss possibility of kidney disease for all PrEP patients starting Truvada®. With individuals who have pre-existing risk factors, consider closer monitoring of creatinine and protein during long term therapy. Preferentially, practitioners treating men or transgender women can initiate Truvada® for PrEP through the Issuance Program and obtain Descovy® for ongoing PrEP through the Patient Assistance Program.

Q: What if the estimated Glomerular Filtration Rate (eGFR) is under 60?

A: Seek physician approval to provide PrEP with Truvada® if the eGFR is under 60 mL per minute. Descovy® is not recommended in individuals with eGFR below 30 mL per minute and is not to be used in women who use their vagina for sex. 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 eGFR is based on lean body weight.

- To estimate lean body weight (male): <https://reference.medscape.com/calculator/lean-body-weight-male>
- To estimate lean body weight (female): <https://reference.medscape.com/calculator/lean-body-weight-female>
- To manually calculate the eGFR: <https://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault>

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Note: for transgender persons not on hormonal therapy, use their gender at birth. If on hormone therapy for more than three months, use their current gender.

For patients considered at increased risk of ongoing HIV infection, consider contacting the Clinical Consultation Center for PrEP (see PrEP Resources and References below)

Q: Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with Truvada® or Descovy®?

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 Truvada®. Drugs that induce p-glycoprotein (such as carbamazepine, oxcarbazepine, phenytoin, rifabutin, rifampin) may interact with Descovy®

Use <https://www.hiv-druginteractions.org/checker> to check for possible interactions.

Additional guidance:

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

<http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/>

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>

<https://www.hivguidelines.org/prep-for-prevention/>

Pre-Exposure Prophylaxis Service (PrEP line): 855-HIV-PrEP[®] (855-448-7737[®]) Clinical Consultation Center at UCSF

Antiretroviral Patient Medication Information Sheets.

<https://aetc.medicine.ufl.edu/resources/drug-information-sheets/>

Telehealth:

Telehealth services for PrEP are available. When anticipating a telehealth PrEP patient please call one of the following staff by starting with the first number in the list below and progressing downward:

1. Administrative Assistant - (O) 239-656-2501; (M) 239-292-3054
2. Telehealth APRN – 239-770-6277
3. HIV AIDS Section Medical Director – 850-519-3734
4. Coverage Team if Administrative Assistant or Telehealth APRN is not available: Clinical Operation Manager – (O) 904-253-1276; (M) 904-349-9303

One of the clinicians noted above will accept the telehealth session and will be the one with whom you establish an audiovisual connection. Before each Telehealth encounter, test the Audio-Visual (A/V) system and problem-solve any connection issues.

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LABORATORY GUIDANCE

| TEST NAME | Initial PrEP Visit | TEST CODE Quest | TEST CODE State | TEST CODE Lab Corp | 1 st Follow-up Visit (3 month/90Day) | 2 nd Follow-up Visit (6 month) | Ongoing Every 90 Day | Ongoing Every 6 months |
|---|--------------------|--|------------------------------|--|---|---|----------------------|------------------------|
| HIV 1/2 Ag/Ab, 4 th gen (preferred) | x | 0091431 | 0500 | 083935 | x | x | x | |
| 3 rd generation rapid HIV test | x | Point of Care Testing (POC) DOH | None | None | | | | |
| Hepatitis Testing | x | 498 HBsAg 499 Anti-HBs 8472 Anti-HCV with reflex | None | 006510 HBsAg 006530 Anti-HBs 144065 Anti-HCV with reflex | | | | |
| Comprehensive Metabolic Panel (CMP) | x | 10231 | Does not run Test | 322000 | x | x | | x |
| RPR w/ reflex to titer or | x | 0092156 | 0250 | 012005 | x | x | x | |
| Syphilis Antibody with cascading reflex | x | 90349 | | 082345 | x | x | x | |
| Chlamydia/GC Amplification (TMA) urine CT/GC - Vaginal swab, endocervical CT/GC - Oral throat swab CT/GC - Rectal swab | x | 11363 11363 70051 16506 | 0430 0430 0430 0430 | 180051 183194 188698 188672 | x | x | x | |
| Urinalysis | x | 0006448 | Does not run Test | 003772 | | x | | x |
| Urinalysis (in-house dip-stick) (POC) | x | CHD | CHD | CHD | | x | | x |
| HCG, Beta subunit, QNT, Serum (pregnancy test) | x | 0008396 | | | x | x | x | |

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|-------------------------------|--------------------|-----------------|-----------------|--------------------|---|---|----------------------|------------------------|
| HCG pregnancy test (POC) | x | CHD | CHD | CHD | x | x | x | |
| APRI Test (AST and Platelets) | | | | 385875 | | | | |

Lab Tests – PrEP Services

Note:

1. Encourage vaccination for hepatitis A and hepatitis B if not immune
2. Annually assess need for ongoing PrEP and repeat hepatitis C screen if indicated.