

Florida Department of Health
At A Glance PrEP Initiation Overview for County Health Departments
As of May 2020

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.

Florida Department of Health
At A Glance PrEP Initiation Overview for County Health Departments
As of May 2020

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.

Florida Department of Health
At A Glance PrEP Initiation Overview for County Health Departments
As of May 2020