

## PRE-EXPOSURE PROPHYLAXIS (PrEP) A Primer for Family Planning and Women's Healthcare Providers

PrEP prescribers include primary care, family planning, OB/GYN and STI (sexually transmitted infection) care providers as well as HIV care providers who also see patients who are not diagnosed with HIV.

Daily emtricitabine 300mg/ tenofovir 200mg (Truvada®) is safe and effective for reducing the risk of HIV acquisition in sexually active people and people who inject drugs.

### WHY IS PrEP A GOOD FIT FOR YOUR FAMILY PLANNING OR WOMEN'S HEALTH PRACTICE?

- You are already having the conversations about sex and risk for pregnancy, HIV and STIs
- Your patients need more options for HIV prevention than just condoms and counseling
- PrEP is intended to be used with, and can enhance, existing prevention modalities
- PrEP significantly reduces risk of HIV transmission for both women and men
- Truvada® is pregnancy category B.

### WHICH PATIENTS MAY BENEFIT FROM PrEP?

Those who are sexually active, HIV negative and answer yes to one of the following questions:

- Use condoms only sometimes or not at all?
- Have sex with one or more than one person whose HIV status they don't know?
- In a relationship with an HIV-positive partner but unaware of their viral suppression status?
- Taken post-exposure prophylaxis (PEP), had an STI, or injected drugs in the past year?

### DISCUSS WHAT YOUR PATIENT IS CURRENTLY DOING TO PROTECT THEMSELVES FROM HIV TRANSMISSION.

Inform your patient about using PrEP as part of their prevention plan to reduce the risk of HIV and STIs. Discuss:

- A longer period of daily PrEP is needed for adequate protection in the female genital tract.
  - 7 days of daily dosing are needed to achieve protective concentrations for receptive anal sex.
  - 20 days of daily dosing for all other activities: insertive anal sex, vaginal sex, and injection drug use.
- Adherence directly correlates to efficacy. It is critical to discuss adherence and suggest adherence strategies.
- Need to immediately report symptoms of acute HIV (fever, fever with sore throat, rash and/or headache).
- Possible side effects: nausea – improves in first few weeks; mild decrease of kidney function - improves when Truvada is discontinued; decreased bone density while on Truvada, no increase in fractures.

### TAKE A MEDICAL & SOCIAL HISTORY, CONDUCT A REVIEW OF SYMPTOMS.

In addition to your standard history and ROS, when prescribing PrEP check for:

- Any history of osteoporosis, renal or liver disease: use caution or avoid using tenofovir.
- Recent symptoms of a mono-like illness (which might indicate seroconversion/[acute HIV infection](#) (AHI)). If present, test for AHI (HIV RNA/viral load or HIV Ag/Ab combo test) and defer PrEP until test results are known.

### OBTAIN PRE-PRESCRIPTION LABORATORY TESTS:

#### Baseline HIV Test

- Obtain 4th generation Ag/Ab combo (recommended) or 3rd generation antibody only (alternative) HIV test
- Perform nucleic acid amplification test (NAAT)/RNA for HIV with patients:
  - Who have symptoms of acute HIV infection (fever, fever with sore throat, rash and/or headache)
  - Who tested negative but have reported unprotected sex with an HIV-positive partner in the last month**(Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP)**

#### Basic Metabolic Panel

- Do not initiate PrEP in patients with creatinine clearance <60 mL/min

#### Urinalysis

- Proteinuria is an early warning sign of tenofovir toxicity; baseline urinalysis identifies pre-existing proteinuria

#### Serology for Viral Hepatitis A, B, and C

- Immunize against hepatitis A and B in non-immune patients
- HBV is not a contraindication to PrEP, but discontinuation requires close monitoring

#### Screening for Sexually Transmitted Infections

- NAAT for gonococcal and chlamydial infection - genital, rectal and pharyngeal screening based on exposure
- Screen for syphilis according to your laboratory's testing algorithm

#### Pregnancy Test

- If patient is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits

## PRESCRIBING RECOMMENDATIONS (Taken from the [New York State \(NYS\) HIV Guidelines](#))

### Prescription for PrEP should not be given until the patient is confirmed to have a negative HIV test result:

All individuals who plan to start PrEP should have a confirmed negative HIV test within 1 week of PrEP initiation. If it has been longer, repeat a 4th generation (recommended) or 3rd generation (alternative) HIV test. A follow-up phone call to discuss test results may be necessary, with the clinician e-prescribing a prescription.

**First Prescription:** 30-day supply with no refills.

**Second Prescription given at 30-day visit:** 60-day supply. 3-month HIV test is required before a 90-day supply can be given. Refer to NYS HIV Guidelines for frequency of other follow-up tests.

**Subsequent Prescriptions:** A negative HIV test is required every 3 months before providing a 90-day supply of PrEP. Refer to the New York State Guideline on PrEP to Prevent HIV Acquisition for frequency of other follow-up tests.

**Recommended Regimen: Truvada 1 tablet PO daily** (Tenofovir 300 mg + Emtricitabine 200 mg)

\* PrEP with antiretroviral agents other than TDF/FTC cannot be recommended at this time.

## WHAT IF MY PATIENT HAS A POSITIVE HIV TEST WHILE ON PrEP?

Immediate linkage to care is essential for any person diagnosed with HIV. For the person with HIV, antiretroviral therapy (ART) dramatically reduces HIV-related morbidity and mortality. Sustained viral suppression helps prevent HIV transmission to sex partners of people with HIV and prevents perinatal transmission of HIV.

- In consultation with an experienced HIV care provider, initiate ART with at least 3 fully active antiretroviral medications and perform HIV genotypic resistance testing. Adjustments can be made according to genotypic resistance results or side effects. **OR**
- Ensure that the patient is **immediately** linked to an HIV-primary care provider for care and prompt initiation of antiretroviral therapy. Confirm with the provider that the patient attended scheduled appointment.
- Submit the NYSDOH HIV/AIDS Provider Reporting Form (PRF – DOH-4189) within 14 days of diagnosis.

## CLINICAL GUIDELINES AND ONLINE RESOURCES:

- [NYS Guideline on PrEP to Prevent HIV Acquisition](#)
- [Pre-PrEP Prescription and PrEP Follow-up Pocket Guides](#) based on NYS PrEP Guideline recommendations.
- [Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis \(PrEP\)](#)
- [NYS Department of Health, AIDS Institute Online Resources for PrEP and nPEP](#)
- **1-hour CME activity:** PrEP is for Women, Too! Oni Blackstock, MD, MHS, Assistant Professor of Medicine, Division of General Internal Medicine, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY <http://www.prn.org/index.php/transmission/article/prep-is-for-women-too>
- **Clinical Education Initiative (CEI) Line - 866-637-2342:** NYS medical providers can use this toll-free number to speak with an experienced clinician regarding PrEP, PEP, HIV, HCV and STI management.

**PrEP Clinical Card:** Includes recommended PrEP regimen, assessment, tests and monitoring and the NYS Clinical Consultation Line phone number.

Order free PrEP cards at: <https://www.surveymonkey.com/r/CEIprovidertools>

If you currently prescribe PrEP or plan to prescribe PrEP and would like to be included in the NYS PrEP/PEP Provider Voluntary Directory, access the simple registration form at: [Directory of NYS PrEP and/ or PEP Providers](#)

If you would like further information about PrEP, please call or email:

Marcia Kindlon, FNP, Director, Clinical Programs, Office of the Medical Director, AIDS Institute. 518-473-8815, [Marcia.Kindlon@health.ny.gov](mailto:Marcia.Kindlon@health.ny.gov)

The full guidance document "[New York State Guideline on PrEP to Prevent HIV Acquisition](#)" should be reviewed prior to prescribing PrEP to your patients. Tools for screening, pretesting, prescribing and follow up can be found in the guidelines document and are available from the CDC.

To receive updates for all NYSDOH Clinical Guidelines, go to: [www.hivguidelines.org/home/about/mailling-list/](http://www.hivguidelines.org/home/about/mailling-list/)

**RECOMMENDED PrEP REGIMEN**

**TRUVADA®**  
(Tenofovir 300 mg + Emtricitabine 200 mg)  
1 tablet PO daily with or without food

**COMMON SIDE EFFECTS:**  
Headache, abdominal pain, weight loss.  
Side effects may resolve or improve after 1st month.

**CONSULT CLINICIAN EXPERIENCED IN MANAGING PrEP IF**  
patient has chronic active HBV,  
is pregnant or attempting to conceive,  
is taking nephrotoxic drugs, or is at risk for bone loss.

**For more information on PrEP go to:**  
[www.hivguidelines.org](http://www.hivguidelines.org)  
[www.ceitraining.org](http://www.ceitraining.org)

To speak with a clinician experienced in managing PrEP  
call the CEI Line at

**cei** **866-637-2342**