

HIV Pre-Exposure Prophylaxis (PrEP) for Medical Providers

If you are diagnosing sexually transmitted infections (STIs) in your patients, then you have patients who are at risk for 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.

WHICH OF YOUR PATIENTS MAY BENEFIT FROM LEARNING ABOUT PREP?

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

Since your last HIV test did you or your partner:

- Have sex without condoms with one or more than one person whose HIV status is unknown?
- Have an STI such as gonorrhea, syphilis or herpes?
- Share needles or injection supplies?
- Have sex with someone living with HIV whose viral suppression status is unknown?

ASK YOUR PATIENTS WHAT THEY ARE DOING TO PROTECT THEMSELVES FROM HIV AND STIs.

Inform your patient about using PrEP to reduce the risk HIV including:

- A longer period of daily medication 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.
- PrEP does not protect against STIs or pregnancy. Use condoms to prevent STIs.

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 or becomes pregnant while on PrEP, discuss the known risks and benefits

This summary is based on the New York HIV Guidelines for the Use of PrEP to Prevent HIV Acquisition. The full document should be reviewed prior to prescribing PrEP to your patients. Tools for screening, pretesting, prescribing and follow up can be found in the Guideline and are also available from the CDC. Links are listed on the following page.

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. 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](#)
- Free: 1-hour CME [“HIV Prevention with Pre-Exposure Prophylaxis”](#) with Demetre Daskalakis, MD:
Better understand approaches to implementation of PrEP in clinical practice using patient scenarios.
- **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

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
www.ceitraining.org

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

cei CLINICAL EDUCATION INITIATIVE **866-637-2342**

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/