WHAT IS nPEP?

Post-Exposure Prophylaxis (nPEP) is a medication taken to prevent acquiring HIV after a possible exposure. nPEP should only be prescribed in emergency situations when a patient indicates that they have had a possible exposure to HIV through unprotected sex, sharing needles, or sexual assault.

nPEP is highly effective when it is started within 72 hours of exposure and consists of a 28-day regimen. The earlier the patient starts on the regimen the better. nPEP is not recommended for individuals who are at increased risk or are exposed to HIV frequently.

PRESCRIBING nPEP

The exposure to HIV should be evaluated by the provider for the potential to transmit HIV based on the type of bodily fluid involved, the route of possible transmission, and the HIV status of the source person. An evaluation of the circumstances of exposure needs to be conducted to determine the date and time of exposure, type, and severity of exposure, details on the incident and exposure sites, and details on the HIV, Hep B, and Hep C status of the source, if known.

RECOMMENDED nPEP REGIMEN:

- The preferred nPEP regimen for otherwise healthy adults and adolescents is: tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) and emtricitabine (F) (200 mg) once daily PLUS raltegravir (RAL) (400 mg) twice daily or dolutegravir (DTG) (50 mg) once daily

- An alternative regimen for otherwise healthy adults and adolescents is: TDF (300 mg) and F (200 mg) once daily PLUS darunavir (DRV) (800 mg) and ritonavir* (RTV) (100 mg) once daily

LABORATORY TESTING AND MONITORING FOR nPEP

Baseline testing for the patient who was exposed includes:

- Perform a physical exam and HIV risk assessment to determine whether nPEP is right for your patient
- Confirm patient is HIV negative (Rapid HIV test or 4th generation antigen-antibody test is preferred)
- Screen for Hepatitis B infection and immunity with surface antibody, surface antigen, and core antibody testing
- Screen for Hepatitis C
- Serum liver enzyme testing
- Blood urea nitrogen/creatinine test
- Test for STIs: rectal, urethral, pharyngeal gonorrhea and chlamydia and syphilis
- Pregnancy testing for all women
- Counsel and assess medication adherence, sexual risk reduction
- Prescription of a 28-day course of nPEP, with weekly check-ins to monitor for side effects and adherence
- Follow-up involves a reassessment of risk, repeat laboratory testing per guidelines including HIV testing at 30 and 90 days to confirm HIV negative status, STI testing if indicated, and possible initiation of PrEP if risk is still present

RISK REDUCTION COUNSELING FOR nPEP

Providers should conduct weekly check-ins with their patients after prescribing nPEP, by phone or in person, to support adherence and encourage other forms of barrier protection throughout the 12-week follow-up period. Once the patient has completed the 28-day regimen they will need a follow-up HIV test at 30 days and again at 90 days to confirm their status. Follow-up involves a reassessment of risk, STI testing if indicated, and possible initiation of PrEP if risk is still present.

PATIENT ASSISTANCE

PrEP - The USPSTF has released guidelines for PrEP with a Grade A recommendation. As a result, qualifying insurance plans are required or encouraged to cover all costs related to PrEP without patient contribution. This includes private, Medicare, and Medicaid plans.

Generally, it is advised to notify patients that, depending on the payor, generic PrEP medication may need to be considered before escalating to higher tier options.

For additional information regarding patient assistance, please refer to our Providers Guide and PrEP Flowsheet. Additional resources include: http://www.getyourprep.com

nPEP is covered by insurance and Medicaid in many states. If the patient is uninsured, they may qualify for an assistance program run by medication manufacturers.

Providers can advocate for patients that are uninsured by applying for co-pay assistance on behalf of the patient or applying for complete coverage for a patient if the patient does not have insurance or needs additional assistance.

Additional resources include:
https://www.gileadadvancingaccess.com
https://www.tevahivgenerics.com
https://www.merckhelps.com

References
https://www.cdc.gov/hiv/basics/prep/about-prep.html · https://www.cdc.gov/hiv/basics/pep/about-pep.html
https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-prep-faq-provider.pdf
https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-pep-faq-provider.pdf
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

HIV TESTING *It's Routine!*

PrEP • nPEP
QUICK REFERENCE GUIDE

After delivery of an HIV-negative result, it is important to evaluate appropriateness for and interest in available prevention strategies, through open discussion of sexual practices and other risk behaviors. A risk reduction plan may include planned re-testing for HIV and other STI's at an appropriate interval, condom use, and PrEP. The CDC estimates that approximately 125,330 Floridians were eligible for PrEP in 2020, and of those about 21,479 benefited from the medication.

R.A.P.I.D RESEARCH AND PREVENTION OF INFECTIOUS DISEASE · AETC AIDS Education & Training Center Program · Florida HEALTH · UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM · UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

FOR MORE INFO OR ASSISTANCE, CONTACT US (305)243-2584

TAKING A SEXUAL HISTORY

A sexual history and risk assessment should be included as part of routine primary care visits for all sexually active patients. When taking a sexual history, it is important to create a safe environment for your patient, assure confidentiality, be sensitive, non-judgmental, and avoid making assumptions about your patient.

Try using the 5 P's of Sexual Health to guide the physical exam:

- **Partners:** "In the past 12 months, how many sexual partners have you had? Men? Women? Both? Transgender?"
- **Practices:** "In the past 12 months, have you had vaginal sex? Oral sex? Anal sex? Are you the receptive partner?"
- **Protection from STIs:** "Do you use condoms consistently? In which situations are you more likely to use a condom?"
- **Past History of STIs:** "When was your last HIV test? Have you ever been diagnosed with an STI, such as gonorrhea, chlamydia, syphilis, herpes, HPV, trichomoniasis, or HIV?"
- **Prevention of Pregnancy:** "Are you using contraception or practicing any form of birth control?"

Based on the patient's risk and preferences, recommending the use of PrEP to prevent HIV may be appropriate.

WHAT IS PrEP?

Pre-Exposure Prophylaxis (PrEP) is a once-daily oral medication taken by HIV-negative individuals to prevent acquiring HIV. PrEP is appropriate for HIV-negative individuals at risk for HIV and those who can adhere to the regimen. PrEP is 99% effective when taken as prescribed. PrEP should be accompanied by a risk reduction plan that includes a conversation around adherence, condoms, testing for STIs, and other methods to reduce risk.

TO WHOM SHOULD I OFFER PrEP?

INDICATIONS FOR PrEP CONSIDERATION:

	SEXUALLY ACTIVE ADULTS & ADOLESCENTS	INJECTION DRUG USERS
DETECTING SUBSTANTIAL RISK OF ACQUIRING HIV INFECTION	• Sexual partner with HIV • Recent bacterial STI • >1 sex partner • History of inconsistent or no condom use • Commercial sex work • Lives in high prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)
CLINICALLY ELIGIBLE	• Documented negative HIV Test before prescribing PrEP • No signs/symptoms of acute HIV infection • Normal renal function, no contraindicated medications • Documented hepatitis B virus infection and vaccination status	

PRESCRIBING PREP

The United States Food and Drug Administration (FDA) has approved three formulations of PrEP for use in HIV prevention in sexually active HIV-negative individuals.

Two formulations of PrEP consist of two antiretroviral medications combined into one oral tablet take daily to prevent HIV:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name **Truvada®**)
  - * People at risk for HIV through receptive vaginal sex are only approved to take F/TDF
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name **Descovy®**)
  - * F/TAF has not yet been studied for HIV prevention for people at risk for HIV through receptive vaginal sex
- Generic PrEP medication (tenofovir disoproxil fumarate/emtricitabine) is now available in the United States and is approved by most insurance plans.
- Cabotegravir (CAB) is a 600 mg injectable formulation for PrEP (brand name Apretude®)

PRESCRIBING AND ADMINISTERING INJECTABLE PREP (CABOTEGRAVIR)

A new injectable medication for PrEP, Cabotegravir (CAB) was recently FDA-approved as a bimonthly intramuscular injection for sexually active men, women, and people of trans experience with indications for PrEP. Cabotegravir for PrEP is recommended for men and women who suffer from renal disease, have problems adhering to an oral regimen or prefer injections over an oral regimen, and represents a significant expansion of PrEP delivery options.

LABORATORY TESTING AND MONITORING FOR PrEP

- Perform a physical exam and HIV risk assessment to determine whether PrEP is right for your patient
- Confirm patient is HIV negative (4th generation antigen-antibody test is preferred)
- Screen for Hepatitis B infection and immunity with surface antibody, surface antigen, and core antibody testing
- Serum liver enzyme testing
- Screen for Hepatitis C
- Blood urea nitrogen/creatinine test
- Test for STIs: rectal, urethral, pharyngeal gonorrhea and chlamydia and syphilis
- Counsel and assess medication adherence, sexual risk reduction
- Limit prescription for oral PrEP medications to 3 months and follow up with patient every 3 months
- Regular follow-up involves a reassessment of risk, repeat laboratory testing per guidelines including HIV testing, STI testing at appropriate intervals, and reissuance of prescription

See https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf for detailed information.