NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (nPEP)

Guidance from the
Michigan Department of Health and Human Services
Bureau of HIV and STI Programs

Revised December 2021

The Michigan Department of Health and Human Services (MDHHS) recognizes that antiretroviral (ARV) therapy initiated soon after exposure to blood, genital secretions, or other potential infectious body fluids that might contain human immunodeficiency virus (HIV), may, in certain circumstances, prevent HIV transmission. Therefore, pursuant to recommendations made by the US Centers for Disease Control and Prevention, MDHHS strongly encourages the administration of antiretroviral post-exposure prophylaxis in the event of non-occupational exposures such as unprotected vaginal or anal sex with a partner living with HIV or of unknown HIV status, sharing of injection drug use equipment, or sexual assault. Furthermore, to facilitate the implementation of this recommendation, MDHHS, in line with the US Public Health Service, recommends that institutions (e.g., emergency departments, urgent care facilities, clinics, health departments) develop clear protocols for the management of nPEP.[1]

What is nPEP?

HIV non-occupational post-exposure prophylaxis (nPEP) involves taking antiretroviral (ARV) medications to reduce, but not eliminate, the possibility of acquiring HIV among individuals who have experienced possible exposures such as:

- unprotected vaginal/anal sex with a partner living with HIV or of unknown HIV status
- sharing injection drug use equipment
- sexual assault

Post-exposure prophylaxis should be started as soon as possible within 72 hours after a known or potential exposure. ARV medications are available only with a prescription from a licensed provider.

The US Public Health Service (PHS) working group recommends prescribing three (or more) tolerable drugs to combat infections following a known or potential exposure to HIV[2]. As of the date of this document, the preferred Adult nPEP regimen that is recommended from CDC is:

Preferred Regimen for Healthy Adults

Tenofovir Disoproxil Fumarate 300 mg with Emtricitabine 200 mg (Truvada) PO once daily for 28 days
***plus* Raltegravir (Isentress) 400 mg PO twice daily for 28 days**
OR
Tenofovir Disoproxil Fumarate 300 mg with Emtricitabine 200 mg (Truvada) PO once daily for 28 days
***plus* Dolutegravir (Tivicay) 50 mg PO once daily for 28 days**

Pregnant women/birthing persons: Dolutegravir is the recommended drug for use in pregnant women/birthing persons. To discuss risk and benefits of prophylaxis for both maternal and fetal health, a prompt consultation with an HIV expert should occur.

In the event of a pediatric exposure, please consult a Pediatric HIV Specialist

Elizabeth E. Secord, MD: Wayne Pediatrics
Email: esecord@med.wayne.edu; Consultation Line (available 24/7): **248-840-4785**

Note: For a list of alternative CDC-recommended nPEP regimens for adults and pediatrics, please reference this link https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf.

For immediate free assistance, please call the ***MDHHS/Henry Ford HIV Consultation Line*** **(313) 575-0332**.

Who is nPEP for?

1. Clinicians should recommend HIV nPEP to individuals who have experienced an exposure to blood, genital secretions, or other potentially infectious body fluids that might contain HIV.

When should nPEP be provided?

2. HIV nPEP should be offered as soon as possible after exposure and initiated no later than 72 hours following exposure. nPEP is **not** recommended for persons who seek care more than 72 hours after exposure **unless** a physician determines that the risk of transmission outweighs the diminished potential benefit of nPEP. For all technical assistance needs regarding nPEP provision, please be sure to contact the **MDHHS/Henry Ford Consultation Line** at **(313) 575-0332.**

In the case of sexual assault:

nPEP should be provided when significant exposure may have occurred. Use of nPEP for sexual assault survivors has been widely encouraged in the United States and elsewhere[3,4,5,6]. A significant exposure is defined by direct contact of the vagina, anus, or mouth[7] with the semen or blood of the alleged assailant, with or without physical injury, tissue damage, or presence of blood at the site of the assault. HIV nPEP should also be offered in cases when mucous membranes or broken skin of the survivor have been in contact with blood or semen of the alleged assailant.

The clinician's decision to recommend HIV nPEP should ***not*** be influenced by the geographic location of the assault or any prior relationship between the victim and perpetrator, but rather by the:

- nature of the exposure during the assault
- readiness of the survivor to initiate and adhere to the regimen
- HIV status of the alleged assailant, if known

If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen, or to make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and schedule a follow-up appointment within 24 hours to discuss further the indications for HIV nPEP.

How is nPEP prescribed?

3. Clinicians should communicate the recommendation for HIV nPEP to the patient simply and clearly, considering their emotional state and ability to comprehend the nature of antiretroviral treatment.

4. Discussion regarding initiation of HIV nPEP should include the following:
    - risk of acquiring HIV
    - potential of nPEP to prevent HIV acquisition
    - possible side effects of the nPEP regimen
    - duration of nPEP
    - monitoring schedule, including follow-up provider visits and labs
    - importance of adherence to the medication regimen
    - plan for accessing the full 28-day supply of appropriate ARVs promptly by way of:
        - prescription filled at a pharmacy that carries the medications
        - pharmaceutical compassionate use and co-pay assistance programs

5. Starter packs (5-7 day supply) of appropriate ARV medications should be available on-site for rapid initiation of HIV nPEP. Sufficient medication should be included in the starter pack to ensure that treatment interruption does not occur

while accessing the recommended 28-day supply. A prescription for the remainder of the full 28-day supply should be provided to the patient when they receive the starter pack. If starter packs are not available, then it is important for sites to have a relationship with a pharmacy that can fill the prescription immediately.

6. Clinicians should obtain blood from the patient for baseline HIV rapid or expedited point of care serologic testing when recommending initiation of nPEP. The provider who obtains baseline HIV testing is responsible for ensuring the result is communicated face-to-face to the patient unless the responsibility is delegated to Partner Service staff at the local health department or to the clinician providing follow-up care if previously agreed.

7. HIV nPEP regimen should be started without waiting for the results of the baseline HIV test; refusal to undergo baseline HIV testing should not preclude initiation of nPEP.

8. For all exposures, other health risks resulting from the exposure should be considered and prophylaxis administered when indicated, such as hepatitis B vaccine, hepatitis C testing and treatment, and testing and treatment for other sexually transmitted infections and pregnancy.

Follow-Up:

9. In addition to a baseline test, all patients seeking care after a potential HIV exposure should be tested for the presence of HIV antibodies/antigens at 4-6 weeks and 3 months after exposure to determine whether HIV infection has occurred.[8] **Patients should be advised where follow-up HIV testing is available to them at no cost.**

10. Patients, particularly those seeking nPEP subsequent to sexual assault, should receive and/or be referred to other prevention or support services, as indicated.

11. When possible, the patient should be linked to an Infectious Disease provider or HIV Specialist by the next business day who can:
    - review the decision to treat
    - evaluate initial drug tolerability
    - reinforce the need for adherence to nPEP
    - arrange for appropriate follow-up care and monitoring.

    Note: nPEP should be initiated as soon as possible and not be delayed or denied based on access to an Infectious Disease Specialist.

12. Patients should be encouraged to practice protective behaviors with sex partners (e.g., abstinence, consistent use of condoms) and drug-use partners (e.g., avoidance of shared injection equipment) throughout the course of nPEP to avoid HIV transmission to others, if they should become infected.

13. Persons who present for repeat courses of nPEP should be considered for pre-exposure prophylaxis (PrEP) after completion of the 28-day nPEP regimen.

Special Considerations:

14. If prophylaxis has been initiated and the sex or needle sharing partner, or in the case of an assault, the assailant, is subsequently found to be HIV negative, nPEP should be discontinued by the provider.

A Note for Healthcare Providers, Emergency Departments and Urgent Care Facilities

Individuals who have experienced non-occupational exposures such as unprotected vaginal or anal sex with a partner of known or unknown HIV status, sharing of injection drug use equipment, or sexual assault, may present in any healthcare setting at any time. Initial exposure management is often overseen by emergency clinicians or other providers who are not experts in the treatment of HIV infection or the use of antiretroviral medications. These providers may not be familiar with either the guidelines for the management of occupational exposures to HIV or the available antiretroviral agents and their relative risks and benefits.

The Michigan Department of Health and Human Services supports the US PHS working group recommendation that institutions develop clear protocols for the management of nPEP[9] including:

- a formal expert consultation mechanism (e.g., the in-house infectious disease consultant or PEPline),
- patient education components,
- appropriate baseline testing,
- identifying and having a starter-pack of an HIV PEP regimen available,
- a process to ensure prompt access to a full 28-day supply,
- a system for follow-up testing, and
- a mechanism to facilitate linkage to follow-up evaluation by an HIV Specialist or other qualified physician.

Healthcare Professional Guidance and Resources:

Expert guidance specific to Michigan is available by contacting the MDHHS/Henry Ford Consultation Program. This program is set up to answer questions from Michigan health care professionals regarding HIV Non-Occupational Post-Exposure Prophylaxis (nPEP), as well as HIV Disease Management, HIV Drug Interactions, HIV Pre-Exposure Prophylaxis (PrEP), and Perinatal HIV Treatment.

Non-urgent questions can be submitted at www.henryford.org/HIVconsult, and will be responded to in 24 to 48 hours.

For urgent questions, health care professionals should contact the 24-hour consultation line by calling (313) 575-0332.

Clinicians may obtain expert guidance in administering nPEP by accessing the PEPline at 1.888.448.4911 or http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.

Other expert guidance:

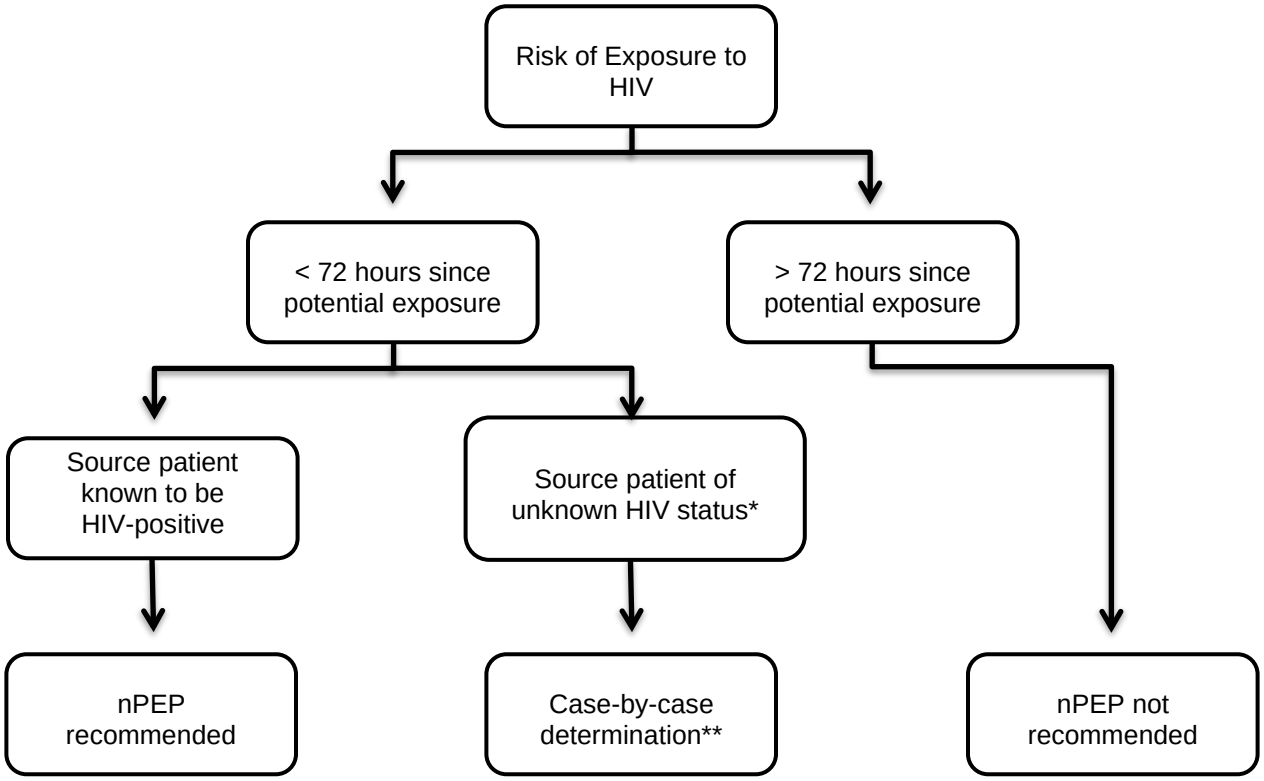
Pediatrics: Elizabeth Secord, MD: Wayne Pediatrics;
Email: esecord@med.wayne.edu; Consultation Line (available 24/7): **248-840-4785**

Midwest AIDS Training and Education Center (MATEC Michigan):
Cell (available 24/7): **313-408-3483**

Urgent Prescription Requests:

MedCart Specialty Pharmacy: **1-877-770-4633, option 1**

- A Clinical Pharmacist is available 24/7 and will respond to emergency voicemails as soon as possible.
- MedCart will assist with same or next day delivery/mail options, payment and benefit options, and more.



* Do not delay nPEP initiation while waiting on HIV testing results

** For any questions, please contact the **MDHHS/Henry Ford HIV Consultation Line** at **(313) 575-0332**

Risk for HIV Acquisition:

Possible exposure sites:
vagina, rectum, eye, mouth, other mucous membranes, nonintact skin, or percutaneous contact

Body fluids that can potentially transmit HIV:
Blood, semen, vaginal secretions, rectal secretions, breast milk, or any bodily fluid that is contaminated with blood

Body fluids that can NOT transmit HIV (if not contaminated with blood):
Urine, nasal secretion, saliva, sweat, tears

References:

[1] Kuhar DT, Henderson, DK, Struble KA, Heneine, W, Thomas, V, Cheever, LW, Gomaa, A, Panlilio, AL. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. *Infect Control Hosp Epidemiol*. 2013 Sep;34(9):875-92. doi: 10.1086/672271.

[2] *Ibid.*

[3] Mayer KH, Kwong J, Church D, et al. HIV prophylaxis after non-occupational exposure in Massachusetts [abstract 220]. Presented at the National HIV Prevention Conference, Atlanta, Georgia, August 29--September 1,1999.

[4] Berrey MM, Schacker T, Collier AC, et al. Treatment of primary human immunodeficiency virus type 1 infection with potent antiretroviral therapy reduces frequency of rapid progression to AIDS. *J Infect Dis* 2001;183:1466--75.

[5] Larkin H, Cosby C, Petti L, Paolinetti L, Harada N. The seroprevalence of HIV and other viral STDs in sexual assault suspects and survivors [abstract]. Presented at the XII International Conference on AIDS, Geneva, Switzerland, June 28-July 3, 1998;12:605.

[6] DiGiovanni C, Berlin F, Casterella P, Redfield R, Hiken M, Falck A. Prevalence of HIV antibody among a group of paraphilic sex offenders [Abstract]. Presented at the VI International Conference on AIDS, San Francisco, California, June 20--24,1990;6:348.

[7] New York State Department of Health, *PEP to Prevent HIV Infection*. Available at NYSDOH AI PEP to Prevent HIV Infection (hivguidelines.org).

[8] "Welcome to CDC Stacks | Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016 - 38856 | Guidelines and Recommendations." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, stacks.cdc.gov/view/cdc/38856.
https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

[9] Kuhar, et al (2013). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis.