Michigan Department of Health & Human Services
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NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (nPEP)

Guidance from the
Michigan Department of Health and Human Services
Division of Health, Wellness & Disease Control

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The Michigan Department of Health and Human Services (MDHHS) recognizes that antiretroviral (ARV) therapy initiated soon after unanticipated sexual contact or injecting drug use 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 high risk, non-occupational exposures such as unprotected vaginal or anal sex with a partner known to be (or possibly) HIV positive, sharing injecting 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) is a preventive treatment strategy that may reduce, but not eliminate, the possibility of becoming infected with HIV among individuals who have experienced high risk exposures such as:

- unprotected vaginal or anal sex with a partner known to be (or possibly) HIV positive,
- sharing injecting drug use equipment, or
- sexual assault.

Post-exposure prophylaxis involves taking antiretroviral medications as soon as possible after exposure. ARVs are available only with a prescription from a physician.

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 is:

Truvada PO daily (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Raltegravir 400 mg PO twice daily

Or

Truvada PO daily (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Dolutegravir 50 mg PO daily

Alternative agents may be used in the presence of drug intolerance, toxicity, or underlying renal disease.

Note: There is no standard regimen for pediatric cases. Recommendations vary based on weight and ability of the child to take pills. Clinicians prescribing nPEP to a child should contact the National PEPline at 1.888.448.4911 or access: http://nccc.ucsf.edu/wp-content/uploads/2014/09/CCC-Guidance-for-Pediatric-HIV-PEP.pdf *for guidance.*

Who is nPEP for?

1. Clinicians should recommend HIV nPEP to individuals who have experienced high risk non-occupational exposures such as unprotected vaginal or anal sex with a partner known to be (or possibly) HIV positive, sharing injecting drug use equipment, or sexual assault.

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

When should nPEP be provided?

2. HIV nPEP should be offered as soon as possible after exposure and initiated, generally, 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 the risk of transmission outweighs the diminished potential benefit of nPEP.)

In the case of sexual assault:

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 further discuss 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 his/her emotional state and ability to comprehend the nature of antiretroviral treatment.

4. Discussion regarding initiation of HIV nPEP should include the:
   - risk of acquiring HIV infection
   - potential of nPEP to prevent HIV infection
   - possible side effects of the nPEP regimen
   - duration of nPEP
   - monitoring schedule, including follow-up
   - 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.

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. This responsibility may be

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, as well as 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 at 6 weeks, 3 months, and 6 months after exposure to determine whether HIV infection has occurred.[8]

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 or consistent use of male condoms) or 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 with repeated high-risk behavior or 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 the patient is pregnant, a full discussion of the benefits and risks of prophylaxis for both maternal and fetal health, as well as prompt consultation with an HIV-expert, should occur.

15. 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.

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

Individuals who have experienced high risk non-occupational exposures such as unprotected vaginal or anal sex with a partner known to be (or possibly) HIV positive, sharing injecting 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 PHS 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 Public Health Service 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.

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/.

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[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.

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[8] Aberg, JA, Daskalakis, DC. Nonoccupational exposure to HIV in adults. In: *UpToDate*, Bartlett, JG (Ed), UpToDate, Waltham, MA. (Accessed on June 8, 2015.)

[9] Kuhar, et al (2013).