ATTENTION: Providers and Office Staff

June 2018 PROVIDER BULLETIN

MDHHS nPEP Guidance

As requested by the Michigan Department of Health and Human Services (MDHHS) UPHP is distributing the attached materials to all UPHP in-network providers. Please see the attached information and distribute as you deem necessary. You can also find this information on our website at http://www.uphp.com/providers/education-tools/provider-bulletins/.

If you have any questions on how MDHHS can support you please contact Dawn Lukomski, HIV Care and Prevention Section Manager at lukomskid@michigan.gov

(This information was distributed via email to all UPHP in-network providers)

NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (nPEP)

Guidance from the
Michigan Department of Health and Human Services
Division of HIV and STD Programs

Revised January 2018

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 of known or unknown HIV status, 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 of known or unknown HIV status
- sharing injecting drug use equipment
- sexual assault

Post-exposure prophylaxis involves taking antiretroviral (ARV) medications as soon as possible after exposure. ARVs 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 Adult nPEP Regimen

A 3-drug regimen (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Raltegravir 400 mg PO twice daily

Or

A 3-drug regimen (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Dolutegravir 50 mg PO daily

Preferred Children Aged 2-12 Years of Age Regimen

A 3-drug regimen (combination of Tenofovir, Emtricitabine, and Raltegravir) with each dosed to age and weight

*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 assistance, please call the Henry Ford HIV Consultation Line (***313-575-0332)***.*

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 of known or unknown HIV status, 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 has 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 outweigh 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 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 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 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.

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/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 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 of known or unknown HIV status, 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 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.

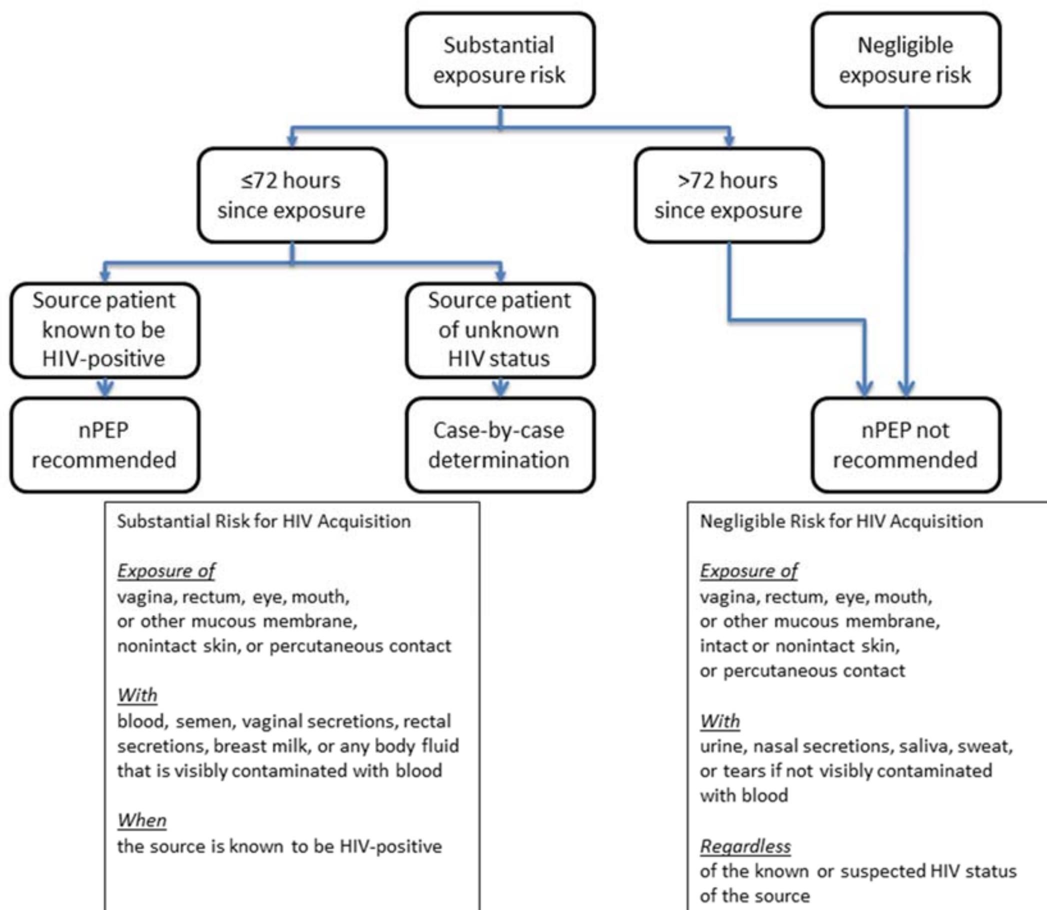
Healthcare Professional Guidance and Resources:

Expert guidance specific to Michigan is available by contacting the 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/.
Non-Occupational Post-Exposure Prophylaxis (nPEP) Algorithm taken from updated CDC guidelines:



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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.

[7] New York State Department of Health, *HIV Prophylaxis for Victims of Sexual Assault*, revised 10/2014. Available at http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-for-victims-of-sexual-assault/. (Accessed on March 25, 2015.)

[8] "Welcome to CDC Stacks | Updated Guidelines for Antiretroviral Post-exposure Prophylaxis after Sexual, Injection Drug Use, or Other Non-occupational 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.
[4] *https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf*
[9] Kuhar, et al (2013).

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

NON-OCCUPATIONAL POST EXPOSURE

Excerpts from the Michigan Department of Health and Human Services nPEP Guidance

Revised January 2018

Individuals who have experienced high-risk non-occupational exposures such as unprotected vaginal or anal sex with a partner of known or unknown HIV status, sharing injecting drug use equipment, or sexual assault, may present in any healthcare setting at any time. The Michigan Department of Health and Human Services supports the US Public Health Service working group recommendation that **institutions** (*e.g., emergency departments, urgent care facilities, community health centers, health departments and those conducting forensic exams following sexual assault*) develop clear protocols for the management of nPEP[1].

1. **nPEP should be recommended** to individuals who have experienced a high-risk, non-occupational exposure such as unprotected vaginal or anal sex with a partner of known or unknown HIV status, sharing injecting drug use equipment, or sexual assault.

   Rationale: Antiretroviral (ARV) therapy initiated soon after unanticipated sexual contact or injecting drug use may, in certain circumstances, prevent HIV transmission.

2. **Providers should prescribe three (or more) tolerable drugs** to combat infections following a known or potential exposure to HIV[2].

Preferred Adult nPEP Regimen

A 3-drug regimen (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Raltegravir 400 mg PO twice daily

Or

A 3-drug regimen (combination of Tenofovir 300 mg and Emtricitabine 200 mg) + Dolutegravir 50 mg PO daily

Preferred Children Aged 2-12 Years of Age Regimen

A 3-drug regimen (combination of Tenofovir, Emtricitabine, and Raltegravir) with each dosed to age and weight

*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 assistance, please call the Henry Ford HIV Consultation Line (***313-575-0332)***.*

3. **HIV nPEP should be offered as soon as possible** after exposure and initiated, generally, no later than 72 hours following exposure.

4. **Discussion with a patient regarding initiation of HIV nPEP** should include the:
   a. risk of acquiring HIV infection
   b. potential of nPEP to prevent HIV infection
   c. possible side effects of the nPEP regimen
   d. duration of nPEP

e. monitoring schedule, including follow-up
f. importance of adherence to the medication regimen
g. plan for accessing the full 28-day supply of appropriate ARVs promptly by way of:
   i. prescription filled at a pharmacy that carries the medications
   ii. 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. 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.

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. 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.[3] **Patients should be advised where follow-up HIV testing is available to them at no cost.**

9. **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.

10. **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.

Pregnant woman: 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.

For more Information:

Access the full MDHHS Guidance on nPEP at:
http://www.michigan.gov/documents/mdch/MDHHS_nPEP_Guidance_6.12.15_-_Final_491813_7.pdf.

Consultation concerning implementation of these guidelines can be obtained from:

-The 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.

-Elizabeth E. Secord, MD: Children's Hospital of Michigan; esecord@med.wayne.edu; 313-745-0203 #2695, beeper; 313-461-5245, cell.
-Mary Rose Forsyth, MWN, WHNP-BC: MATEC Michigan; forsyth@sun.science.wayne.edu; 313-408-3483, cell.
-Jerry Burns, MSN, NP-C: Wayne State University Adult HIV Program; jburns@med.wayne.edu; 313-577-3767, phone.

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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 Post-exposure Prophylaxis. *Infect Control Hosp Epidemiol.* 2013 Sep;34(9):875-92. doi: 10.1086/672271.
[2] *Ibid.*
[3] "Welcome to CDC Stacks | Updated Guidelines for Antiretroviral Post-exposure Prophylaxis after Sexual, Injection Drug Use, or Other Non-occupational 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.
[4] *https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf*