

NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP) IN ADULTS

RESOURCE TOOL

What is nPEP?

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral medications in an attempt to prevent HIV transmission. The nPEP guidelines are recommended for people who may have been exposed to HIV through sex or injection drug use in the past 72 hours to try to prevent HIV infection (see references). For additional information, see <http://www.fcaetc.org/treatments/PrEPPEP.pdf>

- HIV exposure requires urgent medical evaluation. A clinician will assess and determine what treatment is right for each patient after a thorough assessment and evaluation. nPEP is not 100% effective and it does not guarantee that someone exposed to HIV will not become infected with HIV.
- The recommendation for nPEP is tenofovir + emtricitabine (Truvada®) **PLUS** either raltegravir (Isentress®) **OR** dolutegravir (Tivicay®) as the preferred initial nPEP regimen because of its excellent tolerability, proven potency in established HIV infection, and ease of administration. nPEP antiretroviral medications should be taken for a full 4 weeks.

PREFERRED HIV 3-DRUG nPEP REGIMEN

Tenofovir/Emtricitabine 300/200 mg (Truvada®) po daily

PLUS

[Raltegravir (Isentress®) 400 mg po twice a day **OR** dolutegravir (Tivicay®) 50 mg po daily]

For alternative nPEP regimens, see New York State Department of Health AIDS Institute non-occupational post-exposure prophylaxis guidelines (October 2014) at <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/>

At the completion of nPEP, consider Pre-Exposure Prophylaxis (PrEP) in situations where it may be appropriate. PrEP assistance may be found at - <http://www.cdc.gov/hiv/prevention/research/prep/index.html>

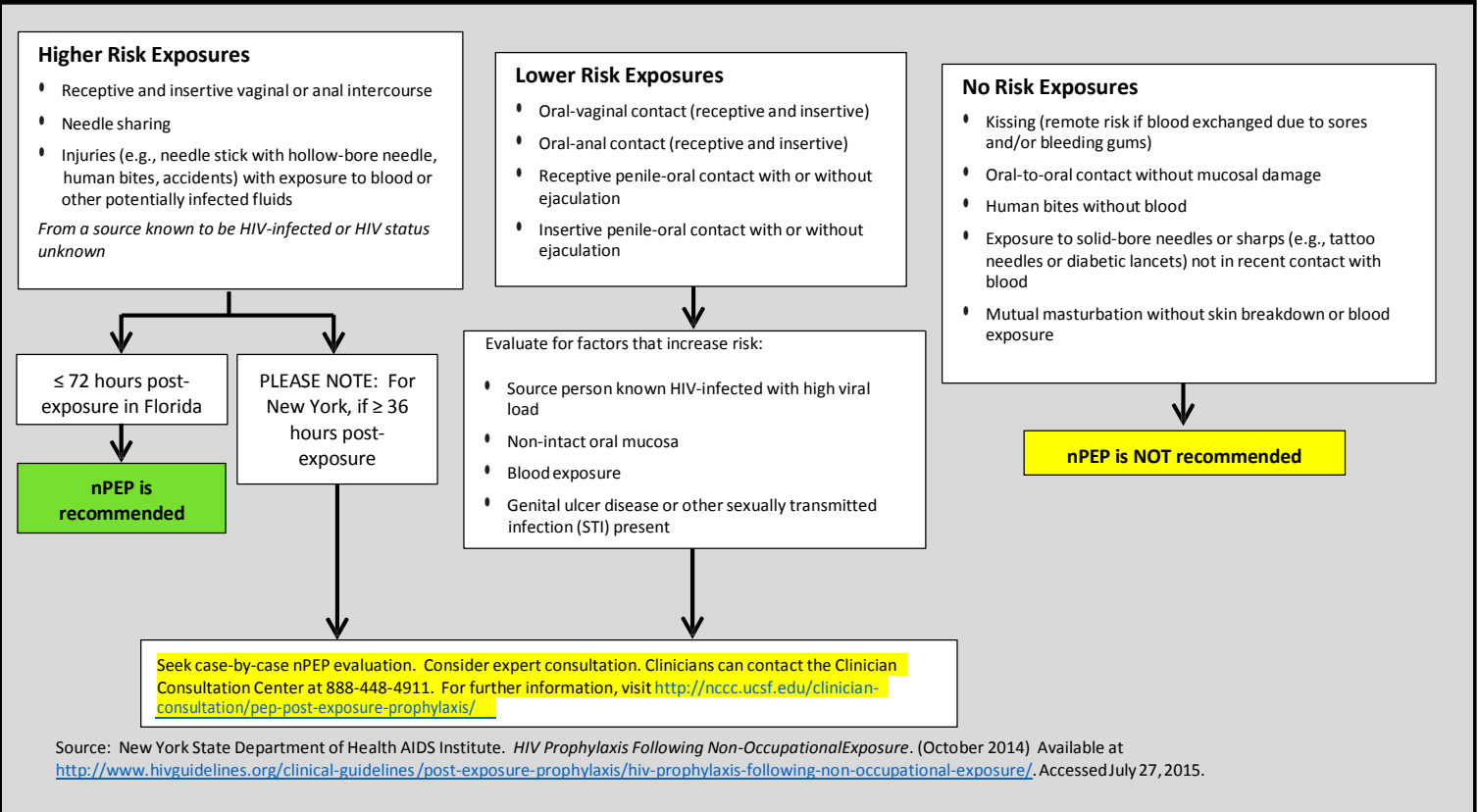
HIV EXPOSURE MANAGEMENT

NOTE: Consider exposure to other blood-borne pathogens (e.g., hepatitis B and C) in addition to HIV. See sections on hepatitis B and C provided in the F/C AETC resource found at <http://www.fcaetc.org/treatments/PrEPPEP.pdf>

Note: Consider exposure to other blood-borne pathogens (e.g., hepatitis B and C) in addition to HIV.

- PEP for non-occupational (nPEP) should start IMMEDIATELY (ideally within 1-2 hours to ≤72 hours post exposure, but can be considered at longer interval with expert consultation). PEP treatment duration of 28 days, or until the source person is determined to be HIV-negative.
- Plasma HIV RNA testing of the source person is recommended in addition to HIV serologic screening if:
 - the source person's HIV screening result is negative but there has been a risk for HIV exposure in the previous 6 weeks or
 - the source person's HIV screening result is positive but the confirmatory antibody-differentiation assay is nonreactive or indeterminate
- Exposed persons should have an HIV antibody test at baseline, 6 weeks, 12 weeks, and 6 months after the exposure. If the 4th generation antigen/antibody test is used, testing can be done at baseline, 6 weeks, and 4 months. This testing should be done regardless of whether the exposed person accepts or declines PEP treatment.
- Risk reduction and primary prevention counseling should be provided whenever someone is assessed for nPEP, regardless of whether PEP is initiated.
- The **Clinician Consultation Center (CCC) 888-448-4911** provides timely answers for urgent exposure management and PEP. Call 9 am – 2 am EST, 7 days a week or see the online PEP Quick Guide for urgent PEP decision-making. See <http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide>. **NOTE*** Calling the CCC in advance of a patient case to **pre-register** your name/information with the Center can decrease the wait time when calling during an urgent situation.
- Callers are encouraged to call the PEpline with any additional or follow-up questions. Emergency calls made between 2 am and 9 am EST and during holiday hours are answered when live service resumes the following morning. See <http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/>
- If nPEP ordered, consider pre-exposure prophylaxis (PrEP) after completion of the 28-day nPEP regimen for those with repeated high-risk behavior or repeated courses of nPEP. PrEP assistance may be located at - <http://www.cdc.gov/hiv/prevention/research/prep/index.html>

Algorithm for Evaluation and Treatment of Possible Non-Occupational HIV Exposures



Non-Occupational Post-Exposure Prophylaxis (nPEP) Payment Options

MEDICAID	<ul style="list-style-type: none"> nPEP is covered (Florida Medicaid)
PRIVATE INSURANCE	<ul style="list-style-type: none"> nPEP coverage is determined by each plan; large co-pay(s) may be a consideration. Co-payment cards are available from the manufacturers. Gilead (Truvada®) - 1-877-505-6986 or www.gileadcopay.com Merck (Isentress®) - 1-855-834-3467 or www.isentress.com ViiV (Tivicay®) - 1-877-784-4842 or www.viivhealthcareforyou.com Patient Access Network Foundation (PAN), a non-profit organization, provides assistance to under-insured patients for their out-of-pocket expenses for HIV treatment and prevention, including PrEP or PEP. Patient's insurance must cover the medication for which patient seeks assistance. Apply online by clicking HERE or call 1-866-316-PANF (7263). http://www.panfoundation.org/
UNINSURED & UNDERINSURED – PATIENT ASSISTANCE PROGRAMS (PAP)	<ul style="list-style-type: none"> Common Patient Assistance Program Application (HIV) at http://hab.hrsa.gov/patientassistance <ul style="list-style-type: none"> HIV meds. are listed by company name with instructions on how to submit the application. You may need to apply to more than one company depending on regimen chosen. See specific application processes in this resource for Gilead, Merck, and ViiV patient assistance programs.
FOR SEXUAL ASSAULT VICTIMS	<ul style="list-style-type: none"> Funding sources may be available to pay for testing and treatment specifically for assault victims. For information about rape crisis services, see HIV Prophylaxis for Victims of Sexual Assault. http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-for-victims-of-sexual-assault/

TRUVADA® (TENOFIVIR + EMTRICITABINE) - nPEP PATIENT ASSISTANCE

OPTION 1: Gilead's Advancing Access Program (1-800-226-2056)

(nPEP Recommended Dose: Tenofovir/Emtricitabine 300/200 mg (Truvada®) po daily x 28 days) and see Isentress® or Tivicay® options below.) Hours are Monday through Friday, 9A – 8P EST

1. Prepare a **Letter of Medical Necessity for nPEP** (see page sample letter in this resource) signed by a clinician, case manager, or victim advocate; Be sure to include patient's name, DOB, PEP medication needed, date of exposure, signature by the clinician, case manager, or victim advocate in the letter.
2. **Fax the Letter of Medical Necessity to 1-800-216-6857.** Indicate the **date and time of day** on the fax coversheet (this is how the fax will be located by the representative later). Do NOT fax a copy of prescription with the letter.
3. Wait for 20 minutes for the fax to be received and processed.
4. To begin the prescreening process over the phone, the clinician, case manager, or victim advocate calls **1-800-226-2056**.
5. In order for the Gilead representative to locate the letter of necessity, have the fax date, time, number of pages faxed, and sender's fax number ready. The representative will ask for information including demographics, clinician name, and possible health insurance. Be sure to have the patient's household size and income available. If patient has no income, information on how patient is being supported will need to be provided. **NOTE:** If the exposure is greater than 72 hours, the client may not be approved for nPEP.
6. Patient signs a consent form for Gilead's assistance; if patient is under 18 years of age, a parent or guardian will provide written consent.
7. If the patient qualifies for the program, the Gilead representative provides voucher, group, and BIN numbers; patient takes this information to a local retail pharmacy and receives a **free 30-day supply of Truvada®**.

OPTION 2: Patient Advocate Foundation (PAF) Co-Pay Relief: non-profit organization, provides assistance to insured patient's only; family income below 400%FPL; <https://www.copays.org/diseases/hiv-aids-and-prevention>

●PAF launched *HIV, AIDS & Prevention CareLine*, call (800) 532-5274 or by web, seeks to connect patients with individualized, case management services free of charge to help with navigating system, coverage options, insurance denials, etc. Online at <https://hivoraidspafcareline.org/>

If the patient has health insurance/Medicare/Medicaid, they can contact/be referred to the Patient Access Network Foundation (PAN) at 866-316-7263 for assistance. **NOTE: If patient has Medicare Part D, they don't qualify for the Co-Pay Program (below), but can apply for PAN Program.**

ISENTRESS® (RALTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION 1: Merck's SUPPORT™ Program (1-800-350-3430) Hours are Monday through Friday, 9A – 6P EST

Isentress® (raltegravir) *Patient Enrollment Form* (application) and instruction page located at http://merckhelps.com/docs/SUP_Enrollment_Form_English.pdf.

Prior to submitting the forms for nPEP, the clinician can call **Merck's SUPPORT™ Program** to alert the **Merck** representative of the need for nPEP and the representative will then start a case file to hasten the approval process.

IMPORTANT: FILL OUT ALL SECTIONS OF APPLICATION COMPLETELY.

1. Patient must be a US resident and have a prescription for ISENTRESS from a health care provider licensed in the U.S.
2. Make sure all demographics and blanks are filled in; if applicant has no insurance, just write *NONE* in section 2.
3. Make sure to indicate where to ship medication (overnight shipping) - either patient's home or physician office. If the enrollment is processed on the same day before 2:30 pm (EST), it can be overnighted. If enrollment is not pulled, processed, and approved BEFORE 2:30 pm (EST), delivery may not be for 48 hours+ as delivery is not guaranteed and delivery times may differ depending on local shipper restrictions. If it's a Friday, may want to have shipped to patient's home, but there is no guarantee it will be delivered on Saturday in any case.
4. TIPS: Patient signs/dates on pages 1 and 2; Clinician fills out prescription in section 3 and makes sure to write quantity #60; Clinician signs/dates section 4.
5. Write "**Prescribing PEP**" in the margins of BOTH pages of the application which flags the application with the urgency of the application.
6. Fax the application to 1-866-410-1913.
7. Wait for 20 minutes after faxing the enrollment form, then the clinician/patient calls 1-800-350-3430 to confirm application was received and will be given further instructions.

OPTION 2: Patient Advocate Foundation (PAF) Co-Pay Relief: non-profit organization, provides assistance to insured patient's only; family income below 400%FPL; <https://www.copays.org/diseases/hiv-aids-and-prevention>; *HIV, AIDS & Prevention CareLine*, call (800) 532-5274; Online at <https://hivoraidspafcareline.org/>

TIVICAY® (DOLUTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION 1: ViiV Patient Assistance Program (1-877-784-4842) Hours are Monday through Friday, 9A – 7P EST

For help completing the application, call ViiV Healthcare Patient Assistance Program at 1-877-7ViiVHC (1-877-784-4842) or go to www.viivhealthcareforyou.com/

1) **PHONE ENROLLMENT**

- provides a means for filling the prescription through a local pharmacy so patient can have quick access to the needed medication, but an **ADVOCATE**, someone involved in the delivery of the patient's healthcare, i.e. a health care provider, social worker, or case worker; NOT a family member or friend, must assist with the process.
- To become an **ADVOCATE**, call ViiV at 1-877-784-4842 and then, as an **ADVOCATE**, you may enroll an nPEP Patient by phone in ViiV's Healthcare Patient Assistance Program (PAP) by phone and assist the nPEP patient to receive up to a 30-day supply of Tivicay® filled through a retail pharmacy.

2) **ENROLLMENT APPLICATION BY THE ADVOCATE**

- Application located at <http://www.viivhealthcareforyou.com/enrollment/enrollment-by-phone.html>. Print out, complete, and sign the ViiV Healthcare Patient Assistance Program enrollment application.
- Gather income documentation, i.e., the first page of Form 1040 tax form or paycheck stubs for the past/most recent 30 days; if retired, a copy of SS letter. If these documents are unavailable, the **ADVOCATE** may certify by signing/dating the "Advocate Certification" that applicant is acting in good faith as reporting accurate income.
- **ADVOCATE** will call 1-877-7ViiVHC (1-877-784-4842) for eligibility screening (to find out if patient is eligible to receive medicine). The **ADVOCATE** faxes completed enrollment form and the proof of income.
 - a. **FOR MEDICARE PART D APPLICANTS:** The program requires the applicant to spend \$600 or more on prescription expenses since January 1st of present calendar year. The **Advocate** and applicant submit a copy of Medicare Part D prescription drug plan card, and pharmacy receipt(s) showing applicant paid at least \$600 for prescriptions in the current calendar, the application, and proof of income.
 - b. **IF PATIENT HAS MEDICARE PART D, BUT DOESN'T HAVE RECEIPTS:** Pharmacist may print out/sign an itemized list of year-to-date patient medication to total at least \$600 if patient did not keep their receipts.
- **Patient goes to the pharmacy to have prescription filled and will need to take the following with them:**
 - a. ViiV Healthcare Patient Assistance Program **voucher** (provided by the Advocate upon completion of enrollment by phone) **and**
 - b. The prescription for 30-day supply of Tivicay®

OPTION 2: Patient Advocate Foundation (PAF) Co-Pay Relief: non-profit organization, provides assistance to insured patient's only; family income below 400%FPL; <https://www.copays.org/diseases/hiv-aids-and-prevention>; HIV, AIDS & Prevention CareLine, call (800) 532-5274; Online at <https://hivoraidspafcareline.org/>

NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP) IN PEDIATRICS/ADOLESCENTS

There are currently no published guidelines for post-exposure prophylaxis from the CDC/PHS specific to the pediatric population. This guidance for pediatric post-exposure prophylaxis (PEP) regimens for known or possible exposures to HIV-infected body fluids can be used pending release of updated non-occupational exposure guidelines that will include pediatric dosing.

PEP REGIMEN OPTIONS: Standard occupational PEP regimens contain 3 drugs. There may be instances where 2 drug PEP is acceptable. The decision to use 2 vs 3 drug PEP must take into consideration a variety of factors which may include, but are not limited to, the risk of the exposure, access to the drugs, cost, pill burden, and tolerability. NOTE: AZT+3TC or TDF+FTC are options to 2-drug PEP. For 3-drug PEP, add either LPV/r or RAL. Read the entire publication at the National HIV/AIDS Clinicians' Consultation Center website - <http://nccc.ucsf.edu/wp-content/uploads/2014/09/CCC-Guidance-for-Pediatric-HIV-PEP.pdf>*

References

- 1) Havens, P. & the Committee on Pediatric AIDS. Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus. American Academy of Pediatrics Clinical Report: Guidance for the Clinician in Rendering Pediatric Care. *Pediatrics*. 2003; 111(6): 1475-1489. Accessed at: <http://pediatrics.aappublications.org/content/111/6/1475.short?rss=1>
- 2) Centers for Disease Control and Prevention. Recommendations and Reports: Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States. Recommendations from the U.S. Department of Health and Human Services. *MMWR*. 2005. Accessed at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>
- 3) Kaufman, M. & the Committee on Adolescence. Care of the Adolescent Sexual Assault Victim. American Academy of Pediatrics Clinical Report. *Pediatrics*. 2008; 122: 462-470. Accessed at: <http://pediatrics.aappublications.org/content/122/2/462.full.pdf>
- 4) Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2010: Sexual Assault and STDs. Accessed at: <http://www.cdc.gov/std/treatment/2010/sexual-assault.htm>
- 5) New York State Department of Health AIDS Institute. HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period. Accessed at: <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period/>

Source: <http://nccc.ucsf.edu/wp-content/uploads/2014/09/CCC-Guidance-for-Pediatric-HIV-PEP.pdf>

Sample *Letter of Medical Necessity*

Re: Obtaining Gilead's Truvada®

Date: _____

To Whom It May Concern,

This letter is written on behalf of patient, _____ (DOB __/__/__), to support and confirm medically the necessity of treatment for non-occupational post-exposure prophylaxis (nPEP). This patient reports possible exposure to the human immunodeficiency virus (HIV) on _____ (date) at _____: _____ (time) a.m. or p.m.

Please expeditiously approve the immediate coverage of emtricitabine/tenofovir (Truvada®) so the patient may begin treatment within the recommended 72-hour treatment initiation period after exposure to HIV occurred.

Sincerely,

<SIGNATURE BY CLINICIAN, CASE MANAGER, OR VICTIM ADVOCATE>

REFERENCES FOR nPEP RESOURCE TOOL

nPEP

National Clinicians' Post-Exposure Prophylaxis Hotline (NCCC PEP Hotline)

For consultation on the treatment of exposures to HIV (and HepB and HepC), the clinician managing the exposed person can call the National HIV/AIDS Clinicians' Post-Exposure Prophylaxis Hotline (PEpline) at 888-HIV-4911. This service is available 7 days a week from 9AM – 2AM at no charge. Additional information is available at the PEpline website - <http://www.nccc.ucsf.edu/>

PEP - Centers for Disease Control and Prevention (CDC). Information about post-exposure prophylaxis (PEP), including who may benefit from receiving PEP, side effects of PEP, and where and how people can get PEP <http://www.cdc.gov/hiv/basics/pep.html>

Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States. Source: CDC's Morbidity and Mortality Weekly Report (MMWR), **January 21, 2005**/Vol. 54/No. RR-2 - <http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf>

Post-Exposure Prophylaxis at AIDS.gov
Information about post-exposure prophylaxis (PEP), including who should take PEP, when PEP should be started, where people can get PEP, and who pays for PEP - <http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>

HIV Clinical Resource, Office of the Medical Director, New York State Department of Health AIDS Institute in collaboration with the Johns Hopkins University Division of Infectious Diseases. Updated **October 2014**
<http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/>

NASTAD Billing Coding Guide for HIV Prevention
<https://www.nastad.org/resource/billing-coding-guide-hiv-prevention>

oPEP

Updated USPHS Guidelines for the Management of Occupational Exposures to HIV and

Recommendations for Postexposure Prophylaxis
Source: *USPHS Working Group on Occupational Postexposure Prophylaxis and National Center for Emerging and Zoonotic Infectious Diseases (U.S.). Division of Healthcare Quality Promotion.* Publish date: **September 25, 2013**
<http://stacks.cdc.gov/view/cdc/20711>

Updated U.S. Public Health Service (USPHS) Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Source: CDC's MMWR, **September 30, 2005**/Vol.54/No. RR-9
<http://www.cdc.gov/mmwr/PDF/rr/rr5409.pdf>
<http://www.jstor.org/stable/10.1086/672271>

Updated UPHS guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis - Recommendations for the management of health care providers who experience occupational exposure to blood and/or other body fluids that might contain HIV. Release date: **September 2013**
<http://www.ncbi.nlm.nih.gov/pubmed/23917901>

HIV Guidelines

Updates to the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents Updated: **April 8, 2015**
<http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0>

Updates to the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents - What's New in the Guidelines Updated: **April 16, 2015**
<http://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/392/whats-new/>