

nPEP Plan of Action Toolkit

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BUREAU OF COMMUNICABLE DISEASES
DIVISION OF DISEASE CONTROL AND HEALTH PROTECTION
FLORIDA DEPARTMENT OF HEALTH

*Non-Occupational
Post-Exposure
Prophylaxis (nPEP)
Resource Materials
for Health Care
Providers*



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FORMS

Sample forms and/or policies are provided by way of example only and are not intended to replace facility policy or legal team guidance and advice.

INTRODUCTION

FOREWORD

This document contains key elements regarding Non-Occupational Post-Exposure Prophylaxis (nPEP) management. Frequent changes in standards of HIV prevention and care require that the guidelines be carefully reviewed by the medical team in your facility to assure that they conform to acceptable local and current approaches. Medical prevention and treatment updates are posted frequently to several websites, including the websites at <http://www.aidsinfo.nih.gov/> and www.cdc.gov/. It is recommended that every provider be familiar with all relevant guidelines.

*This document is not intended to replace clinical research literature or current United States Public Health Service (USPHS) Guidelines, and may not include the full range of prevention and treatment options for all patients. If there are questions regarding the provision of nPEP, it is recommended that a provider contact the **Clinician Consultation Center PEPLINE at 1-888-448-4911**.*

PEP DEFINITION

- **Post-exposure Prophylaxis (PEP)** is the provision of medications to prevent transmission of a disease or illness following an occupational or non-occupational exposure.

TWO TYPES OF PEP

- **Non-occupational PEP (nPEP)** is taken when an individual is potentially exposed to HIV outside the workplace, for example, during episodes of unprotected sex or needle-sharing/injection drug use. Non-occupational exposure is any direct mucosal, percutaneous or intravenous contact with potentially infectious body fluids (not including perinatal situations).
- **Occupational PEP (oPEP)** is taken when an individual working in a health care setting is potentially exposed to products or material(s) that could be or are known to be infected with HIV.

This document presents a plan of action to enable health care providers to address nPEP, the use of HIV medication to reduce the risk of HIV infection after a possible exposure to HIV. Patients presenting for nPEP should be evaluated as soon as possible so treatment, if indicated, can be initiated within recommended timeframes. To be most effective, evidence suggests a 72-hour timeframe for the initiation of nPEP following possible HIV exposure. nPEP initiation should be initiated as soon as possible following the exposure.

CHILDREN AND ADOLESCENTS

These guidelines do not specifically address the special needs of children and adolescents. Refer to New York State Department of Health AIDS Institute's guidance, *HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period*, <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period/> or the American Academy of Pediatric's (AAP) guidance, *Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus* at <http://pediatrics.aappublications.org/content/111/6/1475>.

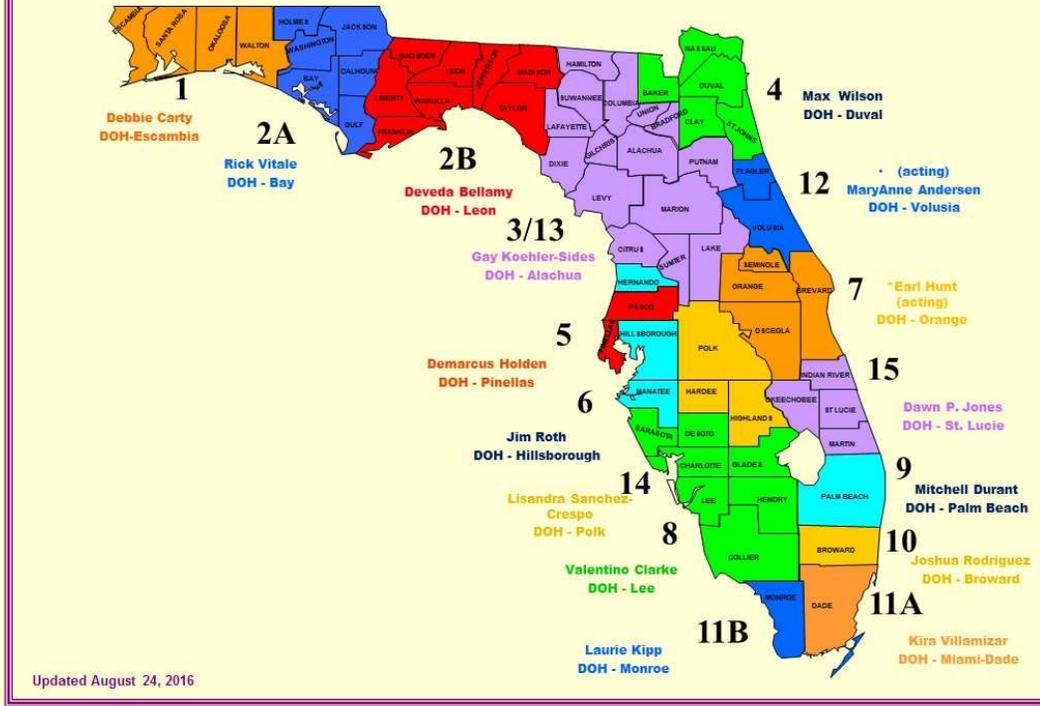
If you are a provider and have questions regarding the provision of nPEP, you can contact the **Clinician Consultation Center PEPLINE** at 1-888-448-4911 or the Southeast AIDS Education and Training Center (SE AETC) (see contact information and map below). Your area HIV/AIDS Program Coordinator (HAPC) can be a useful resource in locating services and resolving patient care issues that may arise in your region.

nPEP Quick Help Card - FLORIDA

For timely answers for urgent HIV exposure management call:

The Clinician Consultation Center PEPLINE - Phone Consultation
(888) 448-4911 / 9:00 a.m. – 2:00 a.m. (EST), seven (7) days a week
<http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/>

Florida HIV/AIDS Program Coordinators



<p>Area 1 Escambia Okaloosa Santa Rosa Walton</p> <p>Debbie Carty DOH-Escambia 1295 W. Fairfield Drive Fenssola, FL 32501 (850) 696-6500 x1500</p>	<p>Area 5 Fasco Pinellas Demarcus Holden DOH-Pinellas 205 Dr. M.L. King Street North St. Petersburg, FL 33701 (727) 824-6900 ext. 4645</p>	<p>Area 11A Dade Kira Villamizar DOH-Miami-Dade STD/HIV Prevention and Control Program 2515 W. Flagler St Miami, FL 33135 (305) 575-5424</p>
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<p>Area 4 Baker Clay Duval Nassau St. Johns</p> <p>Max Wilson DOH-Duval AIDS Program Office 5917 105th Street Jacksonville, FL 32244 (904) 253-2985</p>	<p>Area 9 Palm Beach Mitchell J. Durant, Ph.D. DOH-Riviera Beach 1055 W. 1st Street Room 19 Second floor Riviera Beach, FL 33404 (561) 840-3136</p>	<p>Area 14 Hardee Highlands Polk Lisandra Sanchez-Crespo DOH-Polk 1255 Bone Boulevard Bartow, FL 33830-6735 (863) 519-8242 ext 11191</p>
<p>Area 10 Broward Joshua Rodriguez* DOH-Broward 780 SW 24th Street Ft. Lauderdale, FL 33315 (954) 467-4700, Ext. 5611</p>	<p>Area 15 Indian River Martin Okeechobee St. Lucie Dawn P. Jones DOH-St. Lucie 5150 NW Milner Drive Port St. Lucie, FL 34983 (772) 462-3925</p>	

For HIV/AIDS Program Coordinators contact information, please call Debbie Norberto at (850) 245-4444, ext. 2515, or email at Debbie.Norberto@flhealth.gov.

nPEP ACTION STEPS

1. Evaluation
2. Risk Assessment
3. Treatment
4. Referral, Follow-up and Monitoring

#1 - EVALUATION

Evaluation of the exposed patient should be conducted with the highest level of confidentiality. HIV reporting should take place as required by state laws.

CIRCUMSTANCES OF THE EXPOSURE AND nPEP MANAGEMENT

The following circumstances of the exposure and nPEP management should be recorded in the medical record with details, including:

- **EXPOSURE:** Date and time of exposure (is it within 72 hours?)
- **EXPOSURE TYPE:** Details of the exposure: type and amount of fluid or material and severity of exposure
- **INCIDENT:** Details of the incident: where and how exposure occurred, exposure sites on body
- **SOURCE:** Details about exposure source, if available:
 - HIV, hepatitis B and hepatitis C status
 - If the source is HIV infected, determine the stage of disease, HIV viral load, current and previous antiretroviral therapy and antiretroviral resistance information
- **PATIENT:** Details about the exposed patient:
 - Hepatitis A and hepatitis B vaccination and vaccine-response status
 - Other medical conditions, drug allergies and medications
 - Pregnancy and breast-feeding status

nPEP is not indicated for perceived exposures of negligible or no conceivable risk. Clinicians should be willing to decline requests for nPEP and provide supportive counseling and referrals in these situations.

#2 - RISK ASSESSMENT

The exposure should be evaluated for the potential to transmit HIV based on (1) the type of body substance involved, (2) the route and (3) HIV status of the source patient.

- Decisions should be individualized, weighing the likelihood of transmission against the potential benefits and risks of treatment.
- In sexual assault, the decision to initiate nPEP is based on whether a significant exposure has occurred rather than on the risk behavior of the alleged assailant.
- If the patient is too distraught to engage in a discussion about and/or commitment to the drug regimen at the initial assessment, the clinician should offer a first dose of the medication and make arrangements for a follow up within 24 hours to further discuss the indications for nPEP.

HIV STATUS ASSESSMENT

The likelihood of pre-existing HIV infection should be determined for all individuals presenting for nPEP. The following information should be obtained:

- Has the patient ever been tested, and if so, what was the date/result of their last HIV test?
- The number and types of unprotected exposures since the last HIV test. The likelihood of pre-existing HIV infection should be reviewed with the patient prior to nPEP prescription. If pre-existing HIV infection is likely, this information should be integrated into the risk-benefit assessment.

HIV TESTING OF SOURCE

If the source is available and consents, HIV testing should be completed using an HIV rapid test. If a rapid test is negative or nonreactive for the SOURCE, nPEP should be deferred unless there is a high index of suspicion that the SOURCE may be in the seronegative window period of infection. The seronegative window is up to three months unless 4th generation or newer technology is used, which reduces the window to 15 days on average following the time of exposure. If using a confirmatory test as a backup, nPEP can be discontinued if the result is negative for the SOURCE.

Treatment of the patient is the PRIORITY and should NOT be delayed while waiting for lab results.

EVALUATE THE SOURCE ONLY IF KNOWN/AVAILABLE	
Known HIV infection	Unknown HIV infection
<ul style="list-style-type: none">• Obtain history of antiretroviral medication, recent viral load, CD4 cell count and date of results• Consider evaluation and testing for other sexually transmitted infections, including hepatitis B and hepatitis C	<ul style="list-style-type: none">• Obtain risk history and rapid HIV test (4th generation rapid or serum test preferred)• Consider evaluation and testing for other sexually transmitted infections, including hepatitis B and hepatitis C <p><i>(modified from www.hivguidelines.org)</i></p>

The document, *Risk of HIV Transmission*, found at <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/#APPENDIX B: PROBABILITY OF ACQUIRING HIV FROM A KNOWN HIV-INFECTED SOURCE>, outlines the probability of acquiring HIV from a known source as well as factors that may increase transmission risk. HIV transmission most frequently occurs during sexual or drug-use exposures; however, there are many factors that can influence transmission risk. The probability of transmission when the source person is in the acute and early stage of HIV infection (first six months) has been shown to be 8- to almost 12-fold higher than exposures that take place after the viral set point due to the presence of high HIV viral load levels.^{2,3} The presence of sexually transmitted infections (STIs) in either the source or exposed person also increases risk.⁴⁻⁶ Conversely, transmission risk has been shown to be significantly decreased in source persons who are receiving effective antiretroviral therapy (ART).⁷ To review the CDC HIV Risk Reduction Tool, see <https://www.cdc.gov/hivrisk/estimator.html#>

Adapted from *New York State Department of Health AIDS Institute's UPDATE: HIV Prophylaxis Following Non-Occupational Exposure (10-28-2014)* at www.hivguidelines.org

SEXUAL ASSAULT OR INTRAVENOUS DRUG USERS (IDU)

All exposures sustained during sexual assault should be considered a risk for HIV. nPEP should be considered in all cases of sexual assault, especially in cases where the assailant is unknown. It is reasonable to offer nPEP to patients who have been sexually assaulted by persons who are known to them, but whose sexual and injection drug use history is not known. Multiple other factors can be considered to determine the likelihood that the source of exposure is HIV infected.

The NATIONAL SEXUAL ASSAULT TELEPHONE HOTLINE 1-800-656-HOPE (4673) offers Rape Crisis Center services to mitigate sexual assault trauma.

In Florida, call the Rape Crisis Hotline 1-888-956-7273.

For local service information in Florida, see the Florida Council Against Sexual Violence (FCASV) <https://www.fcasv.org/information/find-your-local-center> or their home website, <https://www.fcasv.org>.

#3 nPEP TREATMENT

PREFERRED nPEP Regimen

Adults and adolescents aged \geq 13 years, including pregnant women, with normal renal function (creatinine clearance \geq 60 mL/min)

RECOMMENDED nPEP REGIMEN

TENOFOVIR DF 300 mg/*EMTRICITABINE 200 mg fixed dose combination (FDC) (TRUVADA®) PO daily
with
RALTEGRAVIR (ISENTRESS®) 400 mg twice daily
or
DOLUTEGRAVIR (TIVICAY®) 50 mg once daily

** Lamivudine 300 mg PO daily may be substituted for emtricitabine. A FDC is available when tenofovir is used with emtricitabine.*

Duration of Therapy

A 28-day course of nPEP is recommended.
Give a three to five-day starter pack at initial visit where available.

ALTERNATIVE nPEP Regimen

Adults and adolescents aged \geq 13 years, including pregnant women, with normal renal function (creatinine clearance \geq 60 mL/min)

ALTERNATIVE nPEP REGIMEN

TENOFOVIR DF 300 mg/*EMTRICITABINE 200 mg fixed dose combination (FDC) (TRUVADA®) once daily
with
DARUNAVIR 800 mg (as two, 400 mg tablets) (PREZISTA®) once daily
and
RITONAVIR 100 mg once daily

** Lamivudine 300 mg PO daily may be substituted for emtricitabine. A FDC is available when tenofovir is used with emtricitabine.*

RENAL INSUFFICIENCY:

The dosing of tenofovir and emtricitabine or lamivudine should be adjusted in patients with baseline creatinine clearance $<$ 50 mL/min. Tenofovir should be used with caution in exposed persons with renal insufficiency or who are taking concomitant nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure.

To view the complete CDC Updated Guidelines for Antiretroviral Post-exposure Prophylaxis after Sexual, Injection Drug Use, or Other Non-occupational Exposure to HIV – United States, 2016, go to: <https://stacks.cdc.gov/view>

More about alternative nPEP regimens at http://nccc.ucsf.edu/wp-content/uploads/2014/04/CCC_PEP_Quick_Guide_Alternative_Regimen_and_Dosing_and_Toxicity_Tables.pdf

PREGNANCY nPEP OPTIONS

If PEP is started for a pregnant exposed person, the recommendation is to call the Clinician Consultation Center at (888) 448-8765 (24 hours, seven days a week) to speak with consultant on Perinatal HIV/AIDS for the most updated options related to pregnancy and breastfeeding.

Other PEP options may be considered in the event of intolerance, source patient with resistant virus, ARV access, or exposed person (EP) preference. In these instances, providers should seek expert consultation. The National HIV/AIDS Clinicians' Consultation Center is accessible at <http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/> or by calling 1-888-448-4911.

STD AND HEPATITIS TREATMENT/VACCINATION

Based upon the 2015 CDC Treatment Guidelines, assessment for STDs may be deferred per the option of the treatment provider and patient. Many specialists recommend preventative therapy at initial examination because follow-up with patients can be difficult.

For STD treatment guidelines, please see https://www.nycptc.org/x/STD_TreatmentTable_2015.pdf

For STD screening recommendations, review https://www.nycptc.org/x/STD_Screening_chart_2015.pdf

HEPATITIS

- Post-exposure hepatitis B vaccination, without HBIG, should adequately protect against HBV infection.
- Hepatitis B vaccination should be administered to patients at the time of the initial examination if they have not previously vaccinated.
- Follow-up doses of vaccine should be administered following recommendations by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) at <http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>
- Hepatitis C testing

EMERGENCY CONTRACEPTION (EC) should be offered if an exposure could result in pregnancy.

PREGNANCY TESTING

- All women of child-bearing potential should be tested for pregnancy.
- If the presenting exposure is vaginal, patient should return for repeat testing if her menstrual cycle is delayed.
- Pregnant women can receive nPEP but should not be given efavirenz or didanosine plus stavudine.
- For more information about antiretroviral use in pregnancy, refer to the *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States* at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5118a1.htm> or www.aidsinfo.nih.gov/guidelines/.

PATIENTS WITH MULTIPLE EXPOSURES

Following a series of exposures, some individuals will present for nPEP both within and outside of the 72-hour nPEP treatment window. It is the decision of the health care provider to determine whether nPEP should or should not be offered in such circumstances.

STARTER PACK

A starter pack of the preferred regimen should be provided at the time of initial evaluation. A starter pack usually consists of a three to five-day supply. NOTE: Medications can be changed at follow up if appropriate based on source patient resistance (if available), efficacy data, toxicity, pill burden/ease of dosing, potential drug interactions, cost and pregnancy risk. Prophylactic antiemetic and antidiarrheal agents can be used if necessary for control of side effects.

LENGTH OF THERAPY AND AMOUNT DISPENSED

The total nPEP treatment is 28 days and should NOT be administered for less than 28 days unless:

- The source is determined to be uninfected via confirmatory HIV test
- The exposed individual is determined to be HIV infected per confirmatory test
- There are intolerable side effects and no alternative medications are available

OR

- Exposed individual changes her/his mind about nPEP after re-examining the risks and benefits
- Individual health care providers should determine a schedule for dispensing nPEP
- If three or more days are missed consecutively, the patient should be advised to discontinue nPEP medication course

PRACTITIONER CONSULTATION WITH A SPECIALIST IS RECOMMENDED

NOTE: If consultation is not immediately available, nPEP should not be delayed; changes can be made as needed after nPEP has been initiated. If the source is found to be HIV negative or nonreactive, nPEP should be discontinued. Delaying nPEP therapy in order to obtain resistance test results (genotyping or phenotyping) for the purpose of selecting more specific therapy is not advised. Exposed persons are frequently unable to complete nPEP regimens due to side effects. Providing prophylactic symptom management can improve adherence.

FOR PRACTITIONER CONSULTATION:

- NCCC nPEP Hotline: 1-888-448-4911
- CDC HOTLINE: 1-800-232-4636
- Southeast AIDS Education and Training Center
Vanderbilt Comprehensive Care Clinic: (615) 875-7873
Taryn Buckley, PhD, CHES or Linda James, MPS: (352) 273-7845
Martia West, MHP, Administrator: (305) 582-2233
<http://aidsetc.org/directory/regional/southeast-aids-education-and-training-center>

4 – REFERRAL, FOLLOW-UP AND MONITORING

All patients receiving nPEP should be re-evaluated within three days of the exposure to review the exposure and available source person data, evaluate adherence and monitor for side effects or toxicities associated with the nPEP regimen. The exposed person should be evaluated weekly while receiving nPEP to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.

Monitoring the exposed patient during nPEP treatment and the follow-up period should be provided by or in consultation with a clinician experienced in managing nPEP. Emergency departments, urgent care centers and other treating health centers should establish linkages with local HIV providers to facilitate easy referral of patients for follow-up care. Providers who do not have access to a clinician experienced in nPEP should use the HIV Clinician Consultation Center PEpline at 1-888-448-4911 for phone consultation. Hours of operation are: 9:00 a.m.–2:00 a.m. EST, seven days a week.

During the treatment period, other blood tests may be indicated to monitor for side effects of treatment. The timing and specific testing indicated varies based on the nPEP regimen used. See the table below from the CDC Guidelines. Clinicians should be aware of the resources available within the community that offer medical and supportive counseling/adherence services following non-occupational exposure. Patients with signs or symptoms of acute HIV infection should be referred for further assessment when nPEP is provided outside of an expert clinical context.

MONITORING RECOMMENDATIONS AFTER INITIATION OF nPEP REGIMENS FOLLOWING NON-OCCUPATIONAL EXPOSURES						
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 12
Clinic Visit	√	√ Or by telephone	√ Or by telephone	√ Or by telephone	√	
Pregnancy Test	√					
Serum liver enzymes, BUN, creatinine, CBC ^a	√		√		√	
HIV Screening Test ^b	√				√	√
STI Screening ^b						
• GC/CT NAAT (based on site of exposure)						
• RPR (See <i>HIV Prophylaxis for Victims of Sexual Assault</i> for recommendations in cases of sexual assault.	√		√ (consider)			
Hepatitis B and C ^d	For post-exposure management for hepatitis B and C, see Section IX: <i>Non-Occupational Exposures to Hepatitis B and C</i>					
^a CBC should be obtained for all exposed persons at baseline. Follow-up CBC at Week 2 and Week 4 is indicated only for those receiving a zidovudine-containing regimen. ^b Recommended even if nPEP is declined.						
Modified from New York State Department of Health AIDS Institute, 2000-2015. All Rights Reserved.						

HIV SEROLOGICAL SCREENING TESTS

A 4th generation HIV antigen/antibody combination test is the recommended serologic screening test. This test is an antibody/antigen combination immunoassay test which can simultaneously detect both HIV-1/HIV-2 antibodies and HIV-1 p24 antigens and will generally be positive within 14–15 days of infection. HIV screening should be confirmed with an FDA-approved HIV-1/HIV-2 antibody-differentiation assay. If the exposed person presents with signs or symptoms of acute HIV seroconversion, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay to diagnose acute HIV infection. (see the *CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens* at <http://www.hivguidelines.org/wp-content/uploads/2014/10/cdc-testing-algorithm-10-10-2014.pdf>).

HIV SEROCONVERSION

If HIV infection develops after an exposure, it will generally occur within two to four weeks of exposure. HIV testing at baseline, 4 weeks, and 12 weeks is recommended after significant exposures, regardless of whether the individual accepts or declines PEP treatment. Point-of-care HIV tests (rapid tests) are less sensitive than laboratory-based HIV tests; therefore, exposed persons should be tested with laboratory-based HIV tests whenever possible.

Patients acutely infected with HIV will often experience at least some symptoms of the acute retroviral syndrome. Fever and flu-like symptoms are common in acute HIV infection but are nonspecific. Rash, mucocutaneous ulcers, oropharyngeal candidiasis and meningismus are more specific. Symptoms may also include fatigue or malaise, joint pain, headache, loss of appetite, night sweats, myalgias, lymphadenopathy, oral and/or genital ulcers, nausea, diarrhea or pharyngitis. Acute HIV infection is often not recognized in the primary care setting because of the similarity of the symptom complex with that of the flu or other common illnesses.

REFERRALS

- Mental health/substance abuse may contribute significantly to the risk of subsequent exposures.
- nPEP should be provided with services that address ongoing needs of patient risk behaviors.
- Providers should be aware of local resources for mental health/substance abuse treatment.
- National Sexual Assault Telephone Hotline: Rape Crisis Center services to mitigate sexual assault trauma (1-800-656-HOPE).
- HIV Hotline for patients in need of HIV-specific support (1-800-CDC-INFO).
- Primary care referrals should also be available, when indicated.

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/>

MAKING REFERRALS FOR nPEP FOLLOW UP

- Option 1: Each facility or clinic provider performing an examination, including sexual assault exams, should solicit a relationship with a qualified medical provider who is knowledgeable about HIV treatment and nPEP and has the ability to receive patients within three to five days of the initial exam and referral.
- Option 2: The initial facility's health care provider/physician may have the patient return to their facility for follow-up treatment if no other option is available.
- Option 3: If there is not an established relationship and/or no physician available, then sexual assault victims who have been assessed by a physician and have met the criteria for nPEP can be referred to another primary care provider or a local infectious disease physician.

PHARMACY CONSIDERATIONS

Pharmacists play a role in the dispensation of nPEP regimens. In order to ensure more timely access of nPEP medications to patients, providers should be aware that the use of "phone-in" oral prescriptions may result in faster dispensing and avoid situations where drug access might be limited. When nPEP is prescribed to a patient receiving other prescription and non-prescription medications, a complete drug profile review should take place to assess for any drug-drug interactions. No medications should be dispensed as part of an nPEP regimen if all medications are unavailable at the same time.

It is beneficial to coordinate with local pharmacies in determining which ones have nPEP medications in stock or can order them quickly. Providers can discuss the treatment with local pharmacies and the need for an urgent response when prescribing nPEP medications. Pharmacists with specific questions regarding nPEP therapy are welcome to contact the PEP Hotline at (888) 448-4911, available seven days a week from 9:00 a.m.–2:00 a.m. EST.

HIV nPEP DISCHARGE INSTRUCTIONS**Medical Record No:**
Name:

The following tests were conducted today:

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> HIV test (rapid / 4 th gen / _____) | <input type="checkbox"/> GC/CT |
| <input type="checkbox"/> Pregnancy test | <input type="checkbox"/> Syphilis/RPR |
| <input type="checkbox"/> CMP | <input type="checkbox"/> eGFR |
| <input type="checkbox"/> Hepatitis B serology _____ | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Hepatitis C serology _____ | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> CBC | <input type="checkbox"/> Other _____ |

The following medications were prescribed today:**HIV Prophylaxis**

You have been given a _____ day starter pack of medications. You will need to follow up with your primary care physician or an infectious disease physician in less than _____ days to receive counseling, blood tests and the remainder of the medication regimen to complete the 28-day dose.

Treatment for Gonorrhea

- Ceftriaxone (Rocephin) 250 mg IM in a single dose **PLUS**
 Azithromycin (Zithromax) 1 gram PO in a single dose

Treatment for Chlamydia

- Azithromycin (Zithromax) 1 gram PO in a single dose **OR**
 Doxycycline 100 mg PO twice a day for 7 days

Emergency Contraception

- Levonorgestrel (Plan B) 0.75 mg tablets: 1 tablet now and 1 tablet in 12 hours at _____

Hepatitis B vaccination

- (Recombivax HB) 0.5 ml IM x 1 dose

Series #1**Series #2** _____**Series #3** _____

During my evaluation, it was determined that I may have been exposed to the HIV virus. I have consented to and been prescribed a 28-day nPEP medication regimen that may help prevent transmission of the HIV virus.

I understand that I need a follow up examination (with my clinic/doctor of choice), and I should bring this sheet so that my health care provider will know what treatment I received and can perform tests to be sure that the medications were effective.

I have been advised that during the 12-week follow-up period, I should:

- Use condoms to prevent sexual transmission
- Avoid pregnancy and breastfeeding
- Avoid needle-sharing
- Refrain from donating blood, plasma, organs, tissue or semen

I have been counseled on taking all of the medications as directed. I was counseled on the need to see a doctor/clinician within three (3) days of my exam. If I do not have a primary physician, I need to contact an infectious disease physician or other medical provider to schedule an appointment.

I will be certain to tell the medical facility with whom I am trying to get an appointment that I may have been exposed to HIV, that I have already started the nPEP medications, and that I need to see a physician within three (3) days of starting this medicine.

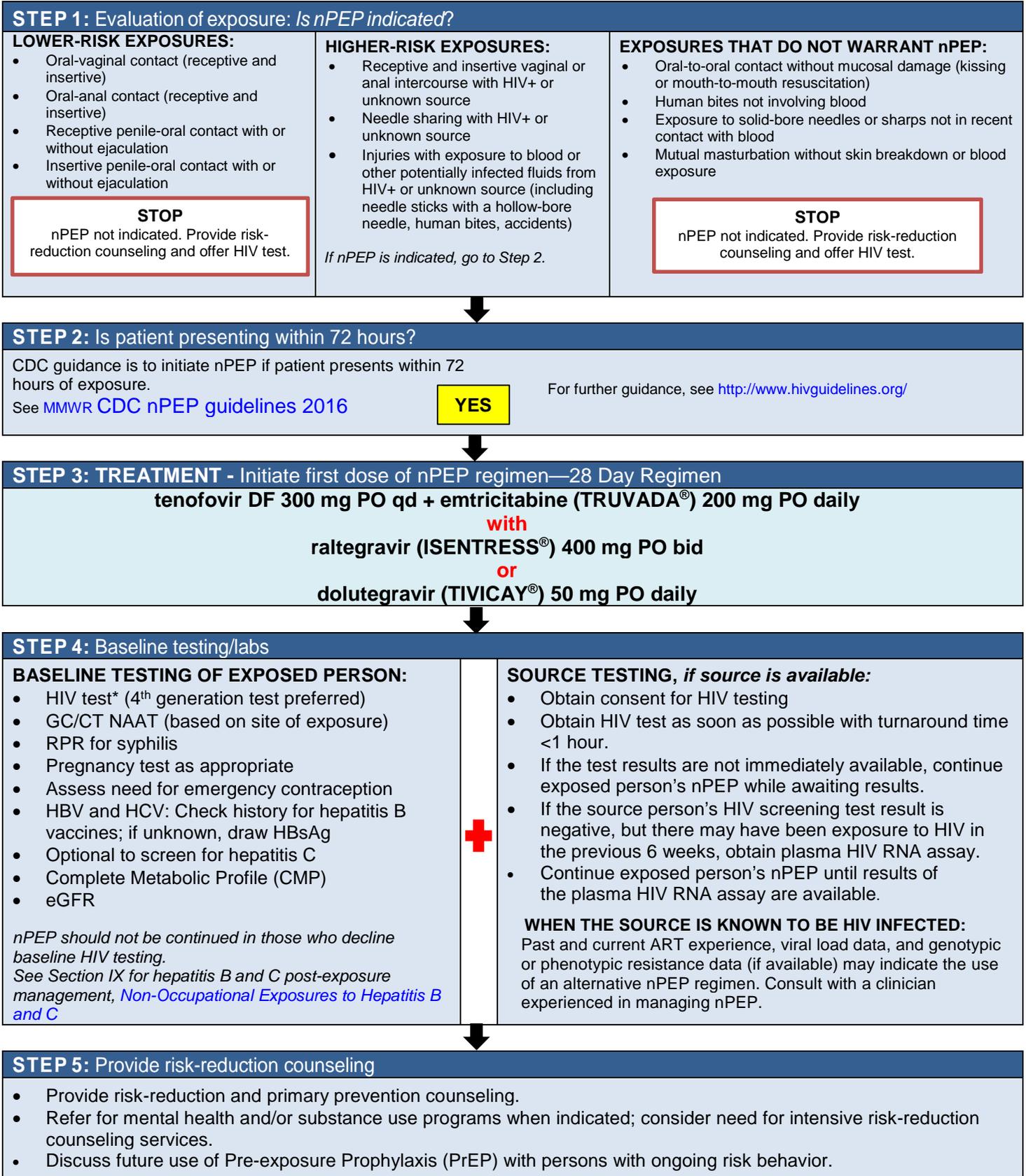
I will take a copy of this form along with my other discharge instructions to my medical provider.

Patient signature: _____**Date:** _____

Modified from Plan of Action for Victims of Sexual Assault, State of Kentucky

Resources and Information for Non-Occupational Post Exposure Prophylaxis (nPEP)

Algorithm for Evaluation and Management for a Non-Occupational Exposure



Modified and adapted from New York Department of Health AIDS Institute <http://www.hivguidelines.org/>

Truvada Medication Information Sheet for Patients

Brand name: Truvada (tru va duh)

Generic name: tenofovir disoproxil fumarate and emtricitabine

Why is this medication prescribed?

- Truvada is one of several medications that are currently used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.
- Truvada is now being used to *prevent* HIV infection.
- Truvada is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection
- When you take Truvada to prevent HIV infection, doctors refer to this use as “pre-exposure prophylaxis” or “PrEP”.

How does Truvada (PrEP) help prevent HIV infection?

- HIV is a virus that attacks your body’s immune cells (the cells that work to fight infections).
- The 2 medications that make up Truvada (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.
- If you take Truvada as PrEP daily, the presence of the medication in your bloodstream can sometimes stop the virus from establishing itself and slow the spread of HIV in your body.
- By itself, PrEP with Truvada does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

How should this medicine be used?

- You must take one tablet of Truvada by mouth every day.
- Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada without talking to your doctor. When your supply of Truvada starts to run low, contact your doctor or pharmacist to get more.
- You may be at higher risk of becoming infected with HIV if you miss doses or stop taking Truvada than if you take it every day.

What special precautions should I follow?

Before taking Truvada (tenofovir and emtricitabine) you must do the following:

- Tell your doctor and pharmacist if you are allergic to tenofovir, emtricitabine, or any other medications.
- Tell your doctor and pharmacist about all prescription and nonprescription medications, (vitamins, nutritional supplements, and herbal products) you are taking. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor if you have or have ever had kidney or liver disease.
- Tell your doctor if you become pregnant or if you are breastfeeding

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB National Prevention

Division of HIV/AIDS Prevention



What special dietary instructions should I follow?

- Continue your normal diet unless your doctor tells you otherwise.

What should I do if I forget a dose?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

You may experience the following side effects while taking Truvada:

- upset stomach
- headache
- vomiting
- loss of appetite

These side effects usually fade during the first month of taking Truvada for PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

Truvada may cause other side effects. Some side effects can be serious. Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- fever or chills especially with
- sore throat, cough, rash or other signs of infection

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (at <http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

How should I store Truvada in my home?

- You should keep Truvada in the container it came in, tightly closed, and out of reach of children.
- You must store it at room temperature and away from excessive heat and moisture.
- Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

What should I do in case of emergency/overdose?

- In case of overdose, call your local poison control center at 1-800-222-1222. If the person has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

- Do not let anyone else take your medication.
- Ask your pharmacist if you have any questions about refilling your prescription.
- Write a list of all of your prescription and over-the-counter medicines, as well as any vitamins, minerals, or other dietary supplements that you take.
- Bring your medication list with you each time you visit a doctor or if you are admitted to a hospital. Keep it with you always in case of emergencies.



TIVICAY® INFORMATION SHEET

Drug Prescribed: **TIVICAY®** 50 MG TAB

Generic Name: DOLUTEGRAVIR TAB 50 MG

Why is this medication prescribed?

Tivicay is a prescription medicine that is used together with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV-1) infection in adults and children who weigh at least 66 pounds.

How does Tivicay work?

Dolutegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

How should this medicine be used?

Stay under the care of a healthcare provider during treatment with Tivicay. Do not run out of Tivicay. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.

What special precautions should I know?

Before you take Tivicay, tell your healthcare provider if you:

- Have ever had an allergic reaction to Tivicay.
- Have had liver problems, including hepatitis B or C infection.
- Have any other medical condition.
- Are pregnant or plan to become pregnant. It is not known if Tivicay will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking

What special dietary instructions should I follow?

Tivicay tablets may be taken with or without food. Continue your normal diet unless your doctor tells you otherwise.

What should I do if I forget a dose?

Take Tivicay exactly as your healthcare provider tells you to take it. If you miss a dose of Tivicay, take it as soon as you remember. Do not take 2 doses at the same time or take more than what your healthcare provider tells you to take.

What side effects does this medication cause?

The most common side effects of Tivicay include:

- Trouble sleeping
- Tiredness
- Headache

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of Tivicay. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Tivicay in my home?

- Store Tivicay at room temperature between 68°F to 77°F (20°C to 25°C).
- The bottle of Tivicay (10-mg tablets) contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. Do not remove the desiccant packet.
- Store Tivicay 10-mg tablets in the original bottle. Keep the bottle tightly closed and protected from moisture.

What should I do in case of emergency/overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222

What other information should I know?

- Some medicines interact with Tivicay. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. You can ask your healthcare provider or pharmacist for a list of medicines that interact with Tivicay.
- Tivicay should be taken at least 2 hours before or 6 hours after you take antacids, laxatives, or other medicines that contain aluminum, magnesium, sucralfate (CARAFATE), or buffered medicines.
- Supplements containing calcium or iron may be taken at the same time with Tivicay if taken with food. Otherwise, Tivicay should be taken at least 2 hours before or 6 hours after you take these medicines.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take Tivicay with other medicines

For detailed information on Tivicay go to www.tivicay.com

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ISENTRESS® INFORMATION SHEET

Drug Prescribed: **ISENTRESS®** 400 MG TAB
Generic Name: RALTEGRAVIR FILM COATED TAB 400 MG



WHY IS IT PRESCRIBED?

ISENTRESS is a prescription HIV medicine used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age

How does ISENTRESS help with HIV?

- Reduce the amount of HIV in your blood. This is called "viral load"
- Increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.
- Reduce the amount of HIV-1 and increase the CD4+ (T) cells in your blood, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

How should this medicine be used?

- Take ISENTRESS exactly as prescribed by your doctor.
- Do not change your dose of ISENTRESS or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor while taking ISENTRESS.
- ISENTRESS film-coated tablets must be swallowed whole.
- ISENTRESS chewable tablets may be chewed or swallowed whole.
- ISENTRESS for oral suspension should be given to your child within 30 minutes of mixing. See the detailed Instructions for Use that comes with ISENTRESS for oral suspension, for information about the correct way to mix and give a dose of ISENTRESS for oral suspension. If you have questions about how to mix or give ISENTRESS for oral suspension, talk to your doctor or pharmacist.
- Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.
- Do not run out of ISENTRESS. Get a refill of your ISENTRESS from your doctor or pharmacy before you run

What special precautions should I follow?

Before you take ISENTRESS, tell your doctor if you:

- Have liver problems
- Have a history of a muscle disorder called rhabdomyolysis or myopathy
- Have increased levels of creatine kinase in your blood
- Have phenylketonuria (PKU). ISENTRESS chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- Have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if ISENTRESS can harm your unborn baby.

What special dietary instructions should I follow?

You may take ISENTRESS with or without food. Continue your normal diet unless your doctor tells you otherwise.

What should I do if I forget a dose?

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more ISENTRESS than prescribed.

What side effects can this medication cause?

The most common side effects of ISENTRESS include:

- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

How should I store ISENTRESS in my home?

Film-Coated Tablets: Store ISENTRESS film-coated tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Chewable Tablets:

Store ISENTRESS chewable tablets at room temperature between 68°F to 77°F (20°C to 25°C). Store ISENTRESS chewable tablets in the original package with the bottle tightly closed. Keep the drying agent (desiccant) in the bottle to protect from moisture.

For Oral Suspension:

- Store ISENTRESS for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the original container. Do not open the foil packet until ready for use.

What should I do in case of emergency/overdose?

If you take too much ISENTRESS, call your doctor or go to the nearest hospital emergency room right away.

What other information should I know?

Avoid taking an antacid that contains aluminum or magnesium within 2 hours before or 2 hours after you take ISENTRESS. This includes antacids such as Acid Gone, Aldroxicon, Alternagel, Di-Gel, Gaviscon, Gelusil, Genaton, Maalox, Maldroxal, Milk of Magnesia, MintoX, Mylagen, Mylanta, Pepcid Complete, Roloids, Rulox, and others. Aluminum or magnesium antacids can make it harder for your body to absorb raltegravir.

For more information, go to www.issentress.com

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BILLING CODES FOR PEP & PREP

OCTOBER 1, 2015, is date set for ICD-10-CM/ICD-10-PCS Implementation: The U.S. Department of Health and Human Services (HHS) issued a rule that ICD-10-CM and ICD-10-PCS will be implemented into the HIPAA mandated code set on October 1, 2015. Click [HERE](#) for AAPC website and [HERE](#) for AMA info.

According to the American Association of Professional Coders (AAPC), the main differences between ICD-9-CM vs. ICD-10-CM are as follows: **ICD-9-CM** has only 13,600 codes, code composition is mostly numeric, with E and V codes alphanumeric, and valid codes have three, four, or five digits. Currently, ICD-9-CM codes are required and no mapping is necessary.

ICD-10-CM has 69,000 codes; composition codes are all alphanumeric, beginning with a letter and with a mix of numbers and letters thereafter; valid codes may have three, four, five, six or seven digits. For a period of two years or more, systems will need to access both ICD-9-CM codes and ICD-10-CM codes as the country transitions from ICD-9-CM to ICD-10-CM. Mapping will be necessary so that equivalent codes can be found for issues of disease tracking, medical necessity edits and outcomes studies.

COMMONLY USED BILLING CODES RELATED TO PEP & PrEP

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	CPT	DESCRIPTION
V69.2	High-risk sexual behavior	Z72.5	High-risk sexual behavior	99401	Preventive counseling (15 minutes)
V01.79	Exposure to other viral diseases (including HIV)	Z20.82	Contact with and (suspected) exposure to other viral communicable diseases	99402	Preventive counseling (30 minutes)
				99403	Preventive counseling (45 minutes)
				99404	Preventive counseling (60 minutes)

ADDITIONAL PEP/PrEP-RELATED BILLING CODES

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	ICD-10	DESCRIPTION
V01	Contact with or exposure to communicable diseases	W46.0	Contact with hypodermic needle (hypodermic needle stick NOS)	B16.2	Acute hepatitis B without delta-agent with hepatic coma
V15.85	Exposure to potentially hazardous body fluid	W46.1	Contact with contaminated hypodermic needle	Z00.0	Encounter for general adult medical examination
E920.5	Needle stick	Z20.8	Contact with and (suspected) exposure to other communicable diseases	Z01.812	Encounter for preprocedural laboratory examination (blood and urine tests prior to treatment or procedure)
V01.8	Exposure to other communicable diseases	Z20.81	Contact with and (suspected) exposure to other bacterial communicable diseases	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
V01.9	Contact with or exposure to unspecified communicable disease	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease	Z11.4	Encounter for screening for human immunodeficiency virus (HIV)
V07.8	Other specified prophylactic measure	Z79	Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes	Z11.59	Encounter for screening for other viral diseases
V58.83	Encounter for therapeutic drug monitoring	Z51.89	Encounter for other specified aftercare	Z11.8	Encounter for screening for other infectious and parasitic diseases
V07.9	Unspecified prophylactic measure	Z51.81	Therapeutic drug level monitoring	Z13.89	Encounter for screening for other disorder (encounter for screening for genitourinary disorders)
42	Human immunodeficiency virus illness or disease with symptoms	Z79.899	Other long term (current) drug therapy	Z13.9	Encounter for screening unspecified
V08	Human immunodeficiency virus infection, asymptomatic	B20	Human immunodeficiency virus (HIV) disease. Includes: AIDS; AIDS-related complex (ARC); HIV infection, symptomatic	Z32.0	Encounter for pregnancy test
70.3	Hepatitis, viral, type B (acute) without hepatic coma	Z21	Asymptomatic human immunodeficiency virus (HIV) infection status	Z70.0	Counseling related to sexual attitude
V02.61	Hepatitis, viral, type B carrier status	Z22.51	Carrier of viral hepatitis B	Z70.1	Counseling related to patient's sexual behavior and orientation
70.32	Hepatitis, viral, type B, chronic	B16.0	Acute hepatitis B with delta-agent with hepatic coma	Z70.3	Counseling related to sexual behavior and orientation of third party (child, partner, spouse)
70.31	Hepatitis, viral, type B, delta	B16.1	Acute hepatitis B with delta-agent without hepatic coma	Z72.51	High-risk heterosexual behavior
ICD-10	Description	B16.9	Acute hepatitis B without delta-agent and without hepatic coma	Z72.52	High-risk homosexual behavior
Z20	Contact with and (suspected) exposure to communicable diseases	B17.0	Acute delta-(super) infection of hepatitis B carrier	Z72.53	High-risk bisexual behavior
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	B18.0	Chronic viral hepatitis B with delta-agent		
Z20.5	Contact with and (suspected) exposure to viral hepatitis	B18.1	Chronic viral hepatitis B without delta-agent		
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus (HIV)				
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids				
W46	Contact with hypodermic needle: "the appropriate 7th character is to be added to each code from category W46" A - initial encounter, D - subsequent encounter, S - sequela				

Adapted and modified from "PrEP Facts" brochure, San Francisco AIDS Foundation, Learn more at PrepFacts.org; American Association of Professional Coders (AAPC) at <https://www.aapc.com/>, and American Medical Assn (AMA) at <http://www.ama-assn.org/ama>

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

MEDICAID	<ul style="list-style-type: none"> nPEP is covered by Florida Medicaid, see http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/paforms/HIV_Diagnosis_Verification_Form.pdf
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 http://www.gileadcopay.com/ Merck (Isentress®) - 1-855-834-3467 or https://www.activatecard.com/7119/# 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 nPEP. Patient insurance must cover the medication for which the patient seeks assistance. Apply online by at https://www.panapply.org/ or call 1-866-316-PANF (7263). http://www.panfoundation.org/ Patient Advocate Foundation: http://www.patientadvocate.org/
UNINSURED & UNDERINSURED PATIENT ASSISTANCE PROGRAMS (PAP)	<ul style="list-style-type: none"> 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 <i>HIV Prophylaxis for Victims of Sexual Assault</i>: http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-for-victims-of-sexual-assault/.

TRUVADA® (TENOFVIR + 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, 9:00 a.m.–8:00 p.m. 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, nPEP medication needed, date of exposure and signature of the clinician, case manager or victim advocate in the letter.
2. Fax the Letter of Medical Necessity to 1-800-216-6857. Make sure you indicate the date and time of day on the fax coversheet (this is how the fax will be located by the representative later). A copy of prescription does not need to be faxed.
3. Wait 20 minutes to be certain the fax has been received and processed. The clinician, case manager or victim advocate then calls 1-800-226-2056 and a representative will begin the prescreening process. The representative will ask for the date, time and number of pages faxed, and your fax number to locate the letter of necessity. Other information collected includes demographics, clinician name and possible health insurance. For the prescreening, have the patient's household size and income available. If no income, will need to provide how the patient is supported.
4. Patient will need to sign a consent form for Gilead's assistance. If patient is under 18 years of age, a parent or guardian will need to provide written consent.
5. If patient qualifies for the program, the representative will provide voucher, group number and BIN number. Patient takes this information to a retail pharmacy of their choice to receive a **30-day supply of Truvada®** at no cost. NOTE: If the exposure is greater than 72 hours, the client may not be approved for nPEP.

OPTION # 2: Patient Access Network Foundation (PAN):

If the patient has health insurance/Medicare/Medicaid, he or she may contact or be referred to the Patient Access Network Foundation (PAN) for assistance. Hours are Monday–Friday, 9:00 a.m. – 5:00 p.m. (EST). Phone: 866-316-7263. NOTE: If the patient has Medicare Part D, he or she can only apply for PAN and not for the Co-Pay Program (below).

Gilead's Co-Pay Coupon Program:

If the patient has commercial insurance, he or she may contact or be referred to Gilead's Co-Pay Coupon Program at 1-877-505-6986. Hours: Monday–Friday 8:00 a.m.–8:00 p.m. EST. The patient is given an authorization number to present with the prescription and other insurance at the pharmacy. For additional co-pay resources, please see <https://www.copays.org/>.

ISENTRESS® (RALTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION # 1: Merck's SUPPORT™ Program (1-800-350-3430)

(nPEP Recommended dose: raltegravir (Isentress®) 400 mg po twice a day x 28 days. See dolutegravir (Tivicay®) option below). Hours are Monday through Friday, 9:00 a.m.–6:00 p.m. EST

Clinician may call **Merck's SUPPORT™ Program** prior to submitting the forms to alert the representative of the need for nPEP. The representative can then create a case number to hasten the approval process. Isentress® (raltegravir) *Patient Enrollment Form* (application) and instruction page located at http://merckhelps.com/docs/SUP_Enrollment_Form_English.pdf.

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 United States.
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's office. If the enrollment is processed on the same day before 2:30 p.m. EST, it can be overnighted. If enrollment is not pulled, processed and approved BEFORE 2:30 p.m. 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 is a Friday, consider shipping to patient's home; however, there is no guarantee it will be delivered on Saturday.
4. Patient signs/dates on pages 1 & 2; clinician fills out prescription in section 3, making sure to indicate quantity #60; clinician signs/dates section 4.
5. Write "**Prescribing PEP**" in the margins of BOTH pages of the application for quicker identification of urgency.
6. Fax to 1-866-410-1913.
7. Clinician/patient should call 1-800-350-3430 to confirm application has been received approximately 20–30 minutes after faxing the enrollment form.

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://hivoraid.pafcareline.org>. Please see <https://www.copays.org/>.

TIVICAY® (DOLUTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION # 1: ViiV Patient Assistance Program (1-877-784-4842) Hours are Monday through Friday, 9:00 a.m.–7:00 p.m. 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 health care, that is, 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. 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, that is, the first page of Form-1040 tax form or paycheck stubs for the most recent 30 days. If retired, a copy of a Social Security letter may be used. 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 determine 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, pharmacy receipt(s) showing applicant paid at least \$600 for prescriptions in the current calendar year, the application and proof of income.
 - b. **IF THE PATIENT HAS MEDICARE PART D, BUT DOESN'T HAVE RECEIPTS:** Pharmacist may print/sign an itemized list of year-to-date patient medication to total at least \$600 if the patient did not keep receipts.
- **Patient goes to the pharmacy to have prescription filled and will need to take the following with them:**
 - a. ViiV Healthcare PAP **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:

If the patient has health insurance; family income below 400% FPL, he or she may access <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://hivoraids.pafcareline.org/>

For additional co-pay resources, please see <https://www.copays.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 three drugs. There may be instances where two-drug PEP is acceptable. The decision to use two versus three 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 two-drug PEP. For three-drug PEP, add either LPV/r or RAL.

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/>

Sample *Letter of Medical Necessity*
for use in 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 post-exposure
prophylaxis.

This patient was exposed to the human immunodeficiency virus (HIV) on
_____ (date) at _____ (time) a.m. or p.m.

Please approve expeditiously the immediate coverage of emtricitabine/tenofovir
(Truvada®) so that the patient may begin treatment within the recommended 72-hour
timeframe of potential HIV exposure.

Sincerely,

Signature

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

HIV NON-OCCUPATIONAL POST-EXPOSURE (nPEP) CHECKLIST

For further information, see guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV available at: www.hivguidelines.org. This checklist is only intended as an aid and expert advice should be sought **before** use.

LAST NAME		FIRST NAME		
DATE	ID	DOB	SEX	ZIP CODE

Was the event a sexual assault? Yes No If Yes, is the assailant known? Yes No COMMENTS:

Date of Exposure / / Time of Exposure : am/pm

CHARACTERISTICS OF EXPOSURE

Sexual contact	Drug Injection Exposure or Non-Sexual
<input type="checkbox"/> Receptive anal sex: <input type="checkbox"/> ejaculation <input type="checkbox"/> withdrawal <input type="checkbox"/> Insertive anal sex: <input type="checkbox"/> circumcised <input type="checkbox"/> uncircumcised <input type="checkbox"/> Receptive vaginal sex <input type="checkbox"/> Insertive vaginal sex: <input type="checkbox"/> circumcised <input type="checkbox"/> uncircumcised <input type="checkbox"/> Receptive oral sex <input type="checkbox"/> Insertive oral sex Other risks: Condoms used? <input type="checkbox"/> Yes <input type="checkbox"/> No Condom <input type="checkbox"/> broke <input type="checkbox"/> slipped <input type="checkbox"/> removed	<input type="checkbox"/> Reuse of injecting equipment <input type="checkbox"/> Other needlestick injury <input type="checkbox"/> Other type <input type="checkbox"/> Superficial <input type="checkbox"/> non-intact skin <input type="checkbox"/> mucous membrane <input type="checkbox"/> Under the influence of alcohol or drugs? Comments:

SOURCE - RISK CHARACTERISTICS

Gender Male Female Transgender

HIV positive	Antiretroviral use	Source HIV risk	Partner	HBV	HCV
<input type="checkbox"/> known	<input type="checkbox"/> no ARV	<input type="checkbox"/> MSM	<input type="checkbox"/> regular	<input type="checkbox"/> +	<input type="checkbox"/> +
<input type="checkbox"/> suspected	<input type="checkbox"/> unknown	<input type="checkbox"/> Injection drug use	<input type="checkbox"/> casual	<input type="checkbox"/> -	<input type="checkbox"/> -
<input type="checkbox"/> unknown	<input type="checkbox"/> past ARV	<input type="checkbox"/> High prevalence area	<input type="checkbox"/> other	<input type="checkbox"/> known risk	<input type="checkbox"/> known risk
<input type="checkbox"/> current ARV	HIV VL: <input type="checkbox"/>	<input type="checkbox"/> unknown	<input type="checkbox"/> partner unknown		

PATIENT - PREVIOUS TESTING

Condition	Result	Date	Condition	Result	Date
<input type="checkbox"/> HIV	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBcAb	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAg	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Syphilis	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAb	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Other STIs	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HepA immune	<input type="checkbox"/> + <input type="checkbox"/> -	

PATIENT - BASELINE TESTING FOLLOWING CURRENT EXPOSURE

Condition	Result	Date	Condition	Result	Date
<input type="checkbox"/> HIV	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBcAb	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAg	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Syphilis	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAb	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> GC/Chlamydia	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> Pregnancy	<input type="checkbox"/> + <input type="checkbox"/> -	
<input type="checkbox"/> Other STIs	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> Blood Chemistry	<input type="checkbox"/> + <input type="checkbox"/> -	

PATIENT - TRIAGE AND nPEP ASSESSMENT

Date / / Time : am/pm Location:	
Post-exposure prophylaxis for HIV recommended? <input type="checkbox"/> Yes <input type="checkbox"/> No	Hepatitis B vaccine / /
nPEP Regimen started? <input type="checkbox"/> Yes <input type="checkbox"/> No	Was patient referred to counselling? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has patient taken nPEP in the last 12 months? <input type="checkbox"/> Yes <input type="checkbox"/> No	If not, reason no referral was made:
Did patient consent to receive nPEP? <input type="checkbox"/> Yes <input type="checkbox"/> No	Follow-up date / /
Date nPEP was received / / Time: : am/pm	Follow-up location <input type="checkbox"/> PCP <input type="checkbox"/> CHD <input type="checkbox"/> CHC <input type="checkbox"/> Other
Drugs prescribed	Dose
	Frequency
	I confirm that the above patient has had an exposure incident that may be a risk for HIV transmission. The result of the assessment for eligibility for HIV nPEP is documented and drugs prescribed.
	Prescriber's Signature:
	Prescriber's Printed Name:
	Provider Number:
Is emergency contraception indicated? <input type="checkbox"/> Yes <input type="checkbox"/> No	Contact Details:
Was PrEP discussed? <input type="checkbox"/> Yes <input type="checkbox"/> No	Telephone:

Modified and adapted from HIV nPEP form at: www.ashm.org.au/pep-guidelines

nPEP RESOURCES

CLINICIAN CONSULTATION CENTER (NCCC)

- For consultation on treatment of exposures to HIV (and HBV and HCV), clinicians managing exposed person(s) can call the Clinician Consultation Center - **Post-Exposure Prophylaxis Hotline (PEPline) at 888-448-4911. This service is available seven days a week from 9 a.m.–2 a.m. EST at no charge.** Additional information is available at the PEPline website, <http://www.nccc.ucsf.edu/>
- US Public Health Service *Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis*, 2013. http://nccc.ucsf.edu/wp-content/uploads/2014/03/Updated_USPHS_Guidelines_Mgmt_Occupational_Exposures_HIV_Recommendations_PEP.pdf
- *PEP HIV Basics* - <http://www.cdc.gov/hiv/basics/pep.html/>
- CDC *Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management*, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm>
- *Get Tested National HIV and STD Testing*. Put in your zip code and it searches for where areas with free testing. <https://gettested.cdc.gov/>
- US Public Health Service (USPHS) *Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*, 2001. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm/>; Appendix A: *USPHS Practice Recommendations for Health-Care Facilities Implementing the Guidelines for Management of Occupational Exposures to Bloodborne Pathogens*, 2001. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a2.htm>

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

- *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, January 21, 2005/Vol. 54/No. RR-2;1-20; <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. Source: CDC's Morbidity and Mortality Weekly Report (MMWR), September 30, 2005/Vol.54/No. RR-9. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>
- National Center for Emerging and Zoonotic Infectious Diseases (U.S.). Division of Healthcare Quality Promotion. Publish dated September 25, 2013. <http://stacks.cdc.gov/view/cdc/20711/>
- *Updated US Public Health Service 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 –dated September 2013. <http://www.ncbi.nlm.nih.gov/pubmed/23917901/>

North Florida & South Florida AIDS Education Training Center (SEAETC.org)

- Pre-Exposure Prophylaxis (PrEP), Non-Occupational Post-Exposure Prophylaxis (nPEP) and Occupational PEP (oPEP) resource tool: <http://www.seaetc.com/wp-content/uploads/2016/06/PrEPPEP-ReferenceCard-20160613.pdf>
- For additional resources, visit www.aetc.medicine.ufl.edu

AIDS.GOV

- 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/>

ASHM.ORG.AU FAIR PRICING COALITION

- <http://www.ashm.org.au/pep-guidelines>
- Patient Assistance Programs and Co-Pay Programs for PEP. <http://fairpricingcoalition.org/patient-assistance-programs-and-co-pay-programs-for-pep/>
- *A Common Patient Assistance Program Application Form for HIV Medicine: Improved and Available*. <http://blog.nastad.org/2013/11/a-common-patient-assistance-program-application-form-for-hiv-medicine-improved-and-available/>

NASTAD

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

REFERENCES

nPEP

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

For consultation on the treatment of exposures to HIV (and hepatitis B and C), 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 seven days a week from 9 a.m.–2 a.m. 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/>

Centers for Disease Control and Prevention, U.S. DHHS - Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV- United States, 2016 -
<http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

oPEP

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

Source: CDC - Authors: *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/>

REFERENCES

Some materials and guidance contained in this document have been modified or adapted from the following resources:

U.S. Public Health Services Guidelines, *Antiretroviral Post-exposure Prophylaxis After Sexual, Injection-Drug Use, or Other Non-Occupational Exposure to HIV in the United States*; DHHS, available at: <http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf>

Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures Recommendations for Health Care Providers in the State of California; Office of AIDS, Department of Health Services.

<https://www.cdph.ca.gov/programs/aids/Documents/RPT2004OfferingPEPFollowingNonOccupExp2004-06.pdf>

Center for Disease Control and Prevention, *Sexually Transmitted Diseases Treatment Guidelines, 2015*; DHHS, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm>

Reprint of Executive Summary from *Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures Recommendations for Health Care Providers in the State of California*; Office of AIDS, Department of Health Services. A full report may be obtained from <http://www.cdph.ca.gov/programs/aids/Pages/Default.aspx>

Havens, P.L., and the Committee on Pediatric AIDS. *Post-Exposure Prophylaxis in Children and Adolescents for Non-Occupational Exposure to Human Immunodeficiency Virus*. *Pediatrics*, 2003 June; 111(6): 1475-1489. <http://pediatrics.aappublications.org/content/111/6/1475>

Merchant, R.C. and Keshavarz, R. *Human Immunodeficiency Virus Post-Exposure Prophylaxis for Adolescents and Children*. *Pediatrics*, 2001 Aug; 108(2):E38 [68]. <http://www.ncbi.nlm.nih.gov/pubmed/11483848>

AAP 2015 Red Book: *Report of the Committee on Infectious Diseases*, 30th Edition, American Academy of Pediatrics. <http://shop.aap.org/Red-Book-2015-Report-of-the-Committee-on-Infectious-Diseases-30th-Edition-Paperback/>

Plan of Action for Victims of Sexual Assault, State of Kentucky, http://kbn.ky.gov/apply/Documents/nPEP_planofaction_FINAL_web_041111.pdf

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RESOURCES USED IN THE PREPARATION OF THIS DOCUMENT

- HIV Prophylaxis Following Non-Occupational Exposure, October 2014, New York State Department of Health AIDS Institute in collaboration with the Johns Hopkins University Division of Infectious Diseases, www.hivguidelines.org/
- Centers for Disease Control and Prevention (CDC) - Preventing New Infections, <http://www.cdc.gov/hiv/guidelines/preventing.html>
- Florida/Caribbean AIDS Education and Training Center <http://www.FCAETC.org>
- Plan of Action for Victims of Sexual Assault, State of Kentucky, http://kbn.ky.gov/apply/Documents/nPEP_planofaction_FINAL_web_041111.pdf
- “PrEP Facts,” San Francisco AIDS Foundation, www.PrePfacts.org
- American Association of Professional Coders (AAPC), <https://www.aapc.com>
- American Medical Assn (AMA), <http://www.ama-assn.org/ama>
- National Guidelines, from the Australasian Society for HIV Medicine (ASHM) www.ashm.org.au/pep-guidelines

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