**Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV (nonoccupational post-exposure prophylaxis [nPEP])
VA Greater Los Angeles Healthcare System**

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## I. Definition: Use of antiretrovirals to prevent HIV infection after sexual, injection-drug use, or other nonoccupational exposure to HIV is referred to as nonoccupational post-exposure prophylaxis (nPEP)

## II. Rationale: data from animal transmission models, perinatal clinical trials, studies of health-care workers receiving prophylaxis after occupational exposures, and observational studies indicate that nPEP can reduce the risk for HIV infection after nonoccupational exposures.

## **III. VA policy**:

* VA providers may prescribe nPEP, i.e., a 30 day supply of triple-drug antiretroviral therapy, to prevent HIV infection in exposed Veteran patients.
* In addition, to nPEP, the VA provides continuous dual-drug antiretroviral therapy as Pre-Exposure Prophylaxis (PrEP) to prevent HIV infection in high-risk persons
* Treatment and testing of source individuals is not permitted unless that individual is also a veteran eligible for VA medical care

## IV. Procedures

* **For questions regarding nPEP, page the Infectious Diseases Fellow on-call** (UCLA pager 310-206-8477 x89321).
* CDC recommendations for nPEP: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00054952.htm>

### Evaluation for nPEP

#### nPEP is recommended if

* The source is known to be HIV-infected.
* Case-by-case decisions should be made for nonoccupational post-exposure prophylaxis (nPEP) made if the HIV status of the source is unknown.
* Testing of source individuals is not permitted at the VA unless that individual is also a veteran eligible for VA medical care.
* The exposure occurred within the prior 72 hours
* The exposure carries a *substantial* risk HIV infection
* Exposure of vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact
* With blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
* When the source is known to be HIV-infected

#### **Type of Exposure Estimated risk per 10,000 exposures to infected source\***

#### Blood transfusion 9,000 90%

#### Needle-sharing injection-drug use 67 0.67%

#### Receptive anal intercourse 50 0.50%

#### Percutaneous needle stick 30 0.30%

#### Receptive penile-vaginal intercourse 10 0.10%

#### Insertive anal intercourse 6.5 0.065%

#### Insertive penile-vaginal intercourse 5 0.050%

#### Receptive oral intercourse 1 0.010%

#### Insertive oral intercourse 0.5 0.005%

##### \* Risks are modified by the height of the viral load in the source patient, the presence of sexually transmitted disease, local inflammation or bleeding, and trauma

#### nPEP is not recommended for exposures with negligible risk of HIV Infection

* Exposure of vagina, rectum, eye, mouth, or other mucous membrane, intact of nonintact skin, or percutaneous contact
* With urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
* Regardless of the known or suspected HIV status of the source

### **Choice of treatment for nPEP**

#### Recommended regimen: Once daily tenofovir AF & emtricitabine & bictegravir (Biktarvy™); do not use Biktarvy™ for CrCl< 30.

#### Alternatives

* **Preferred alternative:** Once daily Darunavir & cobicistat & tenofovir AF & emtricitabine (Symtuza™ single tablet regimen) do not use if CrCl< 30

##### **OR**

* **Other alternative** Once daily rilpivirine & tenofovir AF & emtricitabine (Odefsey™ single tablet regimen); do not be use if on a PPI or CrCl< 30.

##### Note drug-drug interactions with both regimens

#### Renal insufficiency (CrCl < 30): use dose-adjusted zidovudine and lamivudine (DO NOT USE COMBIVIR™) **plus** dolutegravir 50 mg daily

#### Antiretroviral resistance and selection of post-exposure prophylaxis

* An HIV strain is more likely to be resistant to a specific antiretroviral agent if it is derived from a patient who has had an HIV viral load > 500 for 3 – 6 months while receiving antiretroviral therapy.
* Assistance from Infectious Diseases should be sought for management of exposure to HIV that is likely to be resistant to one or more anti-retroviral agents.

#### Contraindicated regimens

* **Abacavir-containing products are CONTRAINDICATED** for use as post-exposure prophylaxis unless B\*5701 testing has been previously performed and HLA B\*5701 has been shown to be absent. Persons with HLA B\*5701 have a 60% risk of developing hypersensitivity reactions which can be severe and fatal. Caution should be taken to not accidentally prescribe TRIUMEQ, which is a combination of dolutegravir with abacavir and lamivudine
* **Post-exposure prophylaxis with nevirapine is CONTRAINDICATED**. Fatal hypersensitivity reactions can occur.

#### Pregnancy

* **Efavirenz is a** **CLASS D AGENT in pregnancy(Positive Evidence of Fetal Risk).**  **Do not use for HIV prophylaxis in pregnancy**, especially during the first trimester or in women of child-bearing potential who are not using effective contraceptives.
* There are no specific contra-indications to the use of other anti-retroviral agents recommended in this document for post-exposure prophylaxis during pregnancy.
* Further information regarding the safety of anti-retroviral agents during pregnancy and the effects of individual agents on the effectiveness of hormonal birth control can be found at <http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/>.

#### Breastfeeding: Breast -feeding is not a contraindication to use of post-exposure prophylaxis, given the high risk of mother-to-infant transmission with acute HIV infection during breast-feeding. To completely eliminate risk, discontinuation of breast-feeding can be considered.

### **C. Dosing recommendations and medication side**

#### Duration: 28 days of therapy should be prescribed

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| **Agent** | **Standard Adult dosage#** | **Side effects and toxicities** |
| *NRTIs - use combination products* |
| Tenofovir AF/emtricitabine(TAF/FTC, Descovy®)May be taken with or without food | 1 tablet once daily200 mg FTC/25 mg TAFDo not use Descovy if CrCl < 30 | TAF: Nausea, vomiting, diarrhea; headache; asthenia; flatulence; and renal impairment FTC: Minimal toxicity; lactic acidosis and hepatic steatosis is a rare but possibly life-threatening event |
| *INSTI (integrase strand transfer inhibitor)*  |
| Biktarvy™May be taken with or without food | 1 tablet once daily(50 mg of bictegravir plus TAF/FTC as above) | Nausea, vomiting, diarrhea; headache; asthenia; flatulence; and renal impairment.  |
| *PIs (protease inhibitors)* |
| Darunavir/cobicistat/TAF/FTC (Symtuza®). Take with food | 1 tablet once daily 800 mg darunavir/150 mg cobicistat/TAF 10 mg/FTC 200 mg  | Diarrhea, nausea, vomiting; asthenia; ↑ transaminases; hyperglycemia; fat redistribution; lipid abnormalities; possible increased bleeding in persons with hemophilia; and pancreatitis |
| *NNRTI (non-nucleoside reverse transcriptase inhibitor* |
| Rilpivirine plus tenofovir AF& emtricitabine (Odefsey™)Take with food | 1 tablet dailyDo not use Odefsey™ if CrCl < 30 | Well toleratedCaution when coadministered with H2 antagonists and antacids; coadministration with proton pump inhibitors is contraindicated |

### # Combination products should be used whenever possible.

### **Baseline laboratory evaluation:**

* Complete blood count, kidney panel and liver panel.
* Test for GC/Chlamydia (urine and swabs of all exposed mucosal surfaces), syphilis, Hepatitis B (surface antigen, surface antibody and core antibody), Hepatitis C and HIV (standard antibody/antigen test plus, for persons with repeated recent high-risk exposure, HIV viral load) – *this testing should be done regardless of whether nPEP is given.*
* Pregnancy testing should be done in all women of child-bearing potential.

### Follow-up

* Give patient a prescription for 30 days of therapy; NO refills
* Consult Infectious Diseases service to evaluate all persons receiving postexposure HIV prophylaxis regimens within 7 days of their start, either in clinic or (preferably) via e-consult.
* Patients living at remote sites (e.g., San Luis Obispo, Santa Barbara, Bakersfield) may be followed by their primary provider in consultation with infectious Diseases
* Laboratory studies
* Complete blood count, kidney panel and liver panel (2-4 weeks after starting nPEP).
* Follow-up HIV testing at 1, 3 and 6 months. Depending on source and patient status, follow-up testing should be done at the same intervals for HBV and HCV.

### **Counselling**: Exposed patients should be advised:

* To use precautions (e.g., use of barrier contraception and avoidance of blood or tissue donations, pregnancy, and, if possible, breast-feeding) to prevent secondary transmission, especially during the first 6–12 weeks after exposure.
* That the GLA Infectious Diseases Clinic provides Pre-Exposure Prophylaxis (PrEP) to prevent HIV infection in high-risk persons including
* Men or women who satisfy any of the following criteria:
* History of inconsistent or no condom use
* High number of sex partners in the past 6 months
* Any sexually transmitted infection (STI) diagnosed or reported in past 6 months
* Being in an ongoing sexual relationship with an HIV-positive partner
* Commercial sex work
* Injection drug users who satisfy any of the following criteria:
* Any sharing in past 6 months of equipment or supplies used to prepare or inject drugs
* Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
* Risk of sexual acquisition (as above)
* *Persons who engage in behaviors that result in frequent, recurrent exposures should be offered PrEP after completing a course of nPEP through the PEP to PrEP consult mechanism*.

## **VI. References**

1. CDC. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States MMWR Recommendations and Reports. 2005;54 (RR2):1-19.
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4. CDC. Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood—France, United Kingdom, and United States, January 1988–August 1994. MMWR 1995;44:929–33.
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6. HIV prophylaxis following occupational exposure. New York State Department of Health AIDS Institute. <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-occupational-exposure/>; updated October 2014, accessed July 3, 2015.
7. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. Infect Control Hosp Epidemiol 2013;34(9):875-892