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Post-Exposure Prophylaxis (PEP) Pre-Exposure Prophylaxis (PrEP) March 2014

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This resource summarizes the guidelines for the management of occupational and non-occupational exposures to the human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV), including recommendations for post-exposure prophylaxis (PEP). Pre-exposure prophylaxis (PrEP) for the prevention of HIV in men who have sex with men (MSM), injecting drug users (IDUs), and heterosexually active adults at high risk for acquiring HIV are also summarized.

Management of Occupational Exposures

Requires immediate reporting so exposed person can be evaluated, tested, and provided with appropriate post-exposure prophylaxis if indicated.
Treatment of Exposure Site
Wash wounds and skin sites with soap and water
Flush mucous membranes with water
Use of antiseptics-not contraindicated, but no evidence that it will further reduce risk of transmission.

Management of Non-Occupational Exposures

Evaluate Exposure - See inside of card
Start non-occupational post-exposure prophylaxis (nPEP) when indicated
Sexual exposure requires evaluation for sexually transmitted infections (STIs)
Women at risk for unintended pregnancy should be offered emergency contraception
Refer as appropriate to counseling for risk-reduction, mental health, substance abuse, and domestic violence
Victims of sexual assault should be referred for additional evaluation and counseling (National Sexual Assault Online Hotline 1.800.656.HOPE [656.4673])

Exposure to other blood-borne pathogens (e.g., hepatitis B and C) should be considered in addition to HIV. See sections on hepatitis B and C provided in this resource.

The information contained in this publication is intended for medical professionals, as a quick reference to the national guidelines. This resource does not replace nor represent the comprehensive nature of the published guidelines.

Visit www.FCAETC.org/treatment for the most up-to-date version of this resource.

CDC Interim Guidance: Pre-Exposure Prophylaxis (PrEP) for Prevention of HIV Infection in Men Who Have Sex with Men (MSM), Injecting Drug Users (IDUs) and Heterosexual Adults

Centers for Disease Control and Prevention (CDC). Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men. MMWR, 2011;60(3), 60-92. Available at: www.cdc.gov/mmwr/pdf/wk/mm6003.pdf. Accessed: March 11, 2014.

CDC. Interim Guidance for Clinicians Considering the Use of Preexposure Prophylaxis for the Prevention of HIV Infection in Heterosexually Active Adults. MMWR, 2012;61(31), 586-589. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm. Accessed: March 11, 2014.

CDC. Update to Interim Guidance for Preexposure Prophylaxis (PrEP) for the Prevention of HIV Infection: PrEP for Injecting Drug Users. MMWR, 2013;62(23);463-465. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm. Accessed: March 11, 2014.

BEFORE INITIATING PrEP

Determine Eligibility

- Negative HIV antibody test immediately before starting PrEP medication
HIV viral load if symptoms of acute HIV infection present or if patient (pt) has had at-risk sexual exposure with an HIV-infected person in the last 30 days
Assess for pregnancy or breastfeeding and discuss pregnancy plans
Confirm that pt is at substantial, ongoing, high risk for acquiring HIV infection
If sexual partner(s) are known HIV-positive, assess if they are in care and on antiretroviral (ARV) therapy and assist if needed
Perform estimated creatinine clearance and assure it is > 60 mL/min. Please visit: www.kidney.org/professionals/kdoqi/gfr\_calculator.cfm for a glomerular filtration rate calculator to estimate renal function.

Other Recommended Actions

- Screen for hepatitis B infection; vaccinate if appropriate, or treat if active infection identified whether or not PrEP prescribed
Sexually transmitted infection (STI) screening and treatment (if needed)
Educate women on the following:
The safety of PrEP medication exposure to infants during pregnancy has not been fully assessed but no harm reported to date and
PrEP should not be prescribed for breastfeeding women

BEGINNING PrEP MEDICATION REGIMEN

- Review factors that can help identify individuals at high risk for sexually acquired HIV-1 and important prescribing considerations
Review "Agreement Form for Initiating TRUVADA® for Pre-Exposure Prophylaxis (PrEP) of Sexually Acquired HIV-1 Infection" with your pt
Prescribe Truvada® (300 mg tenofovir [TDF]/200 mg emtricitabine [FTC]) po once daily
Prescribe no more than a 90-day supply, and renew only if HIV antibody test or fourth generation antibody/antigen test confirms that pt remains HIV-uninfected
Perform pregnancy test. Assure the pt has been informed about the benefits and risk of use should pregnancy occur as well as the need to avoid breastfeeding.
Consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention
Provide risk-reduction and PrEP medication adherence counseling and condoms

- 1. Gilead Sciences, Inc. TRUVADA® for a Pre-exposure Prophylaxis (PrEP) Indication: Risk Evaluation and Mitigation Strategy (REMS). June, 2013. Available at: www.truvadapreprems.com. Accessed: March 11, 2014.
2. Gilead Sciences, Inc. Agreement Form for Initiating TRUVADA® for Pre-exposure Prophylaxis (PrEP) of Sexually Acquired HIV-1 Infection. June, 2013. Available at: www.truvadapreprems.com/Content/pdf/Agreement\_Form.pdf. Accessed: March 11, 2014.
3. CDC. Use of this drug for prevention of parenteral HIV acquisition in those without sexual risk is "off label". MMWR. 2013; 62(23);463-465. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm. Accessed: March 11, 2014.

FOLLOW-UP AT LEAST EVERY 90 DAYS WHILE PATIENT TAKING PrEP

- Document negative HIV antibody test or fourth generation antibody/antigen test
Document negative pregnancy test; if pregnant discuss ongoing PrEP (unknown risks) with pt and prenatal care provider and report exposure to antiretroviral pregnancy registry (www.apregistry.com)
Assess and discuss PrEP medication adherence and consider more frequent follow-up visits if inconsistent adherence is identified
STI symptoms assessment and testing and treatment as indicated at each follow-up visit; at 6 month intervals screen for STIs without regard to symptoms
Three months after PrEP start, and every 6-12 months thereafter, evaluate serum creatinine and estimated creatinine clearance (www.kidney.org/professionals/kdoqi/gfr\_calculator.cfm). Dose adjust per package insert and monitor phosphorous if renal insufficiency present.

ON DISCONTINUING PrEP

- HIV antibody test or fourth generation HIV antibody/antigen testing
If HIV-positive, baseline HIV genotype and linkage to care
If HIV-negative, assure continued risk-reduction support services as indicated
If active hepatitis B is diagnosed, assure continued hepatitis B treatment
If pregnant, inform prenatal care provider of TDF/FTC use in early pregnancy

Post-Exposure Prophylaxis for Hepatitis B Virus (HBV)

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 2001;50(RR-11): 1-53. Available at: www.cdc.gov/mmwr/pdf/rr/r5011.pdf. Accessed: March 11, 2014.
CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. MMWR, 2013;62(RR-10): 1-19. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm?\_cid=rr6210a1\_w. Accessed: March 11, 2014.

Management of Exposures to HBV

- Any blood or body fluid exposure to an unvaccinated person should lead to the initiation of the hepatitis B vaccine series, unless they have not responded after a second complete vaccination series (after two 3-dose series)
Recombivax HB® 10 mcg or Engerix-B® 20 mcg IM at 0, 1, and 6 months (Consider 40 mcg dose if exposed person is on dialysis or is immunocompromised)
When Hepatitis B Immune Globulin (HBIG) is indicated, it should be administered as soon as possible after the exposure (preferably within 24 hours, but is recommended up to 1 week following an occupational exposure)
HBIG can be administered simultaneously with the Hepatitis B vaccine, but at a separate site
Test for Hepatitis B surface antibody (HBsAb) 1-2 months after last dose of vaccine series or booster, adequate HBsAb ≥ 10 mIU/mL (>0.99 index value)
Persons who have HBsAb < 10 mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure from a source pt who is HBsAg (+) or has an unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later
Baseline testing consists of hepatitis B surface antibody (HBsAb), hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) total
Testing at 6 months consists of HBsAg and HBcAb total

Table with 3 columns: EXPOSED PERSON'S IMMUNE STATUS, TREATMENT (Source HBsAg (+), HBsAg (unknown) or Not Available for Testing), and TREATMENT (Source HBsAg (-)). Rows include Unvaccinated or Incomplete Vaccination, Vaccinated-responder (HBsAb ≥ 10 mIU/mL), Vaccinated-nonresponder (HBsAb < 10 mIU/mL), and Vaccination Completed (HBsAb response unknown).

4. Give vaccine booster dose; check antibody response (HBsAb quantitative) 1-2 months later; give additional 2 doses (for total of 6 doses) if HBsAb remains < 10 mIU/mL and repeat HBsAb 1-2 months later.

Post-Exposure Management for Hepatitis C Virus (HCV)

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 2001;50(RR-11), 1-53. Available at: www.cdc.gov/mmwr/pdf/rr/r5011.pdf. Accessed: March 11, 2014.
CDC. Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965. MMWR, 2012;61(4) 1-34. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf. Accessed: March 11, 2014.
CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. MMWR, 2013;62(18), 357-365. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm. Accessed: March 11, 2014.

Management of Exposures to HCV

- Perform hepatitis C virus antibody test (HCV Ab) for the exposure source5; if source is an injection drug user or immunocompromised, consider adding HCV viral load testing
Perform baseline testing for HCV Ab and alanine transaminase (ALT) activity for the exposed person
Perform follow-up testing:
HCV Ab and ALT activity at 4-6 months or
HCV viral load at 4-6 weeks for earlier detection
Confirm HCV Ab results reported positive by testing for HCV viral load

Post-Exposure Management for HCV

- No regimens proven beneficial for PEP
Early identification of acute HCV and referral to hepatitis C specialist for management if infected

5. CDC. Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965. MMWR, 2012;61(4) 1-34. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf. Accessed: March 11, 2014.

Report Adverse Events and Pregnancy Exposures

- FDA MedWatch: Report unusual or severe toxicity to antiretrovirals www.fda.gov/Safety/MedWatch/HowToReport/default.htm 800.FDA.1088 (332.1088)
Antiretroviral Pregnancy Registry: A voluntary prospective, exposure-registration, observational study designed to collect and evaluate data on the outcomes of pregnancy exposures to antiretroviral products. www.apregistry.com 800.258.4263

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National Clinicians' Post-Exposure Prophylaxis Hotline 888.HIV.4911 (448.4911)

An up-to-date and downloadable PDF file is available online at www.FCAETC.org/treatment. To order additional printed copies, please email orders@fcaetc.org. IF YOU REQUIRE AN ALTERNATE FORMAT TO ACCOMMODATE A DISABILITY, please email contact@fcaetc.org or call 866.352.2382. ALSO AVAILABLE FOR ORDER AND DOWNLOAD: ARV Therapy in Adults & Adolescents, ARV Therapy in Pediatrics, Hepatitis and HIV/AIDS, Opportunistic Infections (OIs) in HIV/AIDS, Oral Manifestations Associated with HIV/AIDS, Post-Exposure Prophylaxis (PEP) in Pediatrics/Adolescents, Treatment of Sexually Transmitted Diseases (STDs) in HIV-Infected Patients, Treatment of Tuberculosis (TB) in HIV/AIDS

## 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 this resource.

- HIV Post-Exposure Prophylaxis (PEP) for both non-occupational and occupational exposures should be started **IMMEDIATELY** (ideally within 1-2 hours), when indicated, after HIV exposure and continued for 28 days, or until the source person is determined to be HIV-negative. PEP can be considered after 24-36 hours of the exposure with expert consultation.
- The National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) 888.448.4911 offers treating clinicians up-to-the-minute advice on managing occupational exposures (e.g., needlesticks, splashes, etc.) to HIV, hepatitis and other blood-borne pathogens
- PEPline clinicians will respond to your call between 9 a.m. and 2 a.m. EST
- For urgent occupational exposure needs, please call during these hours or see the PEPline Guidances for Occupational Exposures. Callers are encouraged to call the PEPline with any additional or follow-up questions. Emergency calls made between 2 a.m. and 9 a.m. EST and during holiday hours are answered when live service resumes the following morning. See: <http://nccc.ucsf.edu/clinician-consultation/post-exposure-prophylaxis-peg/>.

### Non-Occupational Post-Exposure Prophylaxis (nPEP) for HIV

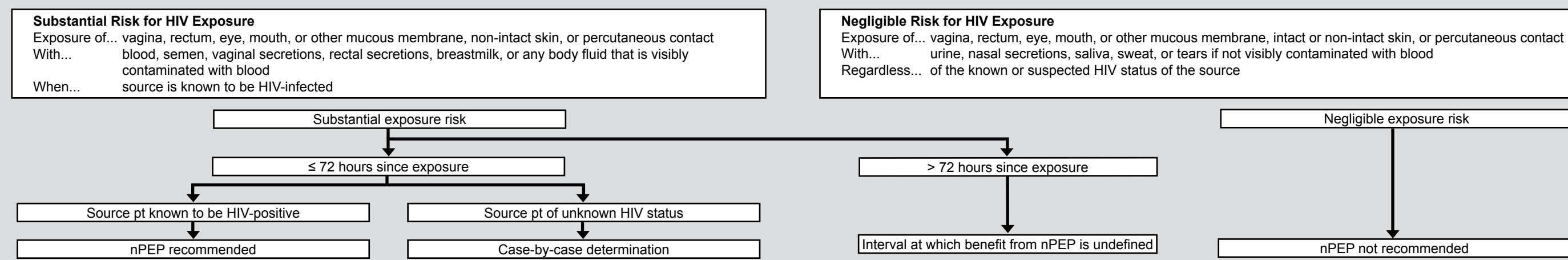
CDC. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. *MMWR*, 2005;54(No. RR-2).

Available at: [www.aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf](http://www.aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf). Accessed: March 11, 2014.

Health Resource and Service Administration (HRSA). Nonoccupational Postexposure Prophylaxis. (January 2011). Available at: [http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302\\_nonoccupational\\_peg.html](http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302_nonoccupational_peg.html). Accessed: March 11, 2014.

The guidelines recommend offering nPEP to persons presenting within 72 hours of unanticipated sexual or injection-drug use HIV exposure to prevent transmission. It is most cost-effective following highest risk exposures (e.g., when sex partner is known to be HIV-infected or after receptive anal intercourse with a homosexual or bisexual man of unknown serostatus). Obtain complete blood count (CBC), liver function tests (LFTs), and creatinine and estimated glomerular filtration rate (GFR) at baseline before treatment with ARV medications. Guidelines emphasize the importance of providing counseling on risk-avoidance and risk-reduction to decrease future exposures to HIV. Exposed person should have a baseline HIV antibody test performed and repeat antibody testing at 4-6 weeks, 3 months, and 6 months. Testing for other STIs, hepatitis B and C, and pregnancy should be offered. When given, nPEP should be continued for 28 days.

#### Algorithm for Evaluation and Treatment of Possible Non-occupational HIV Exposures



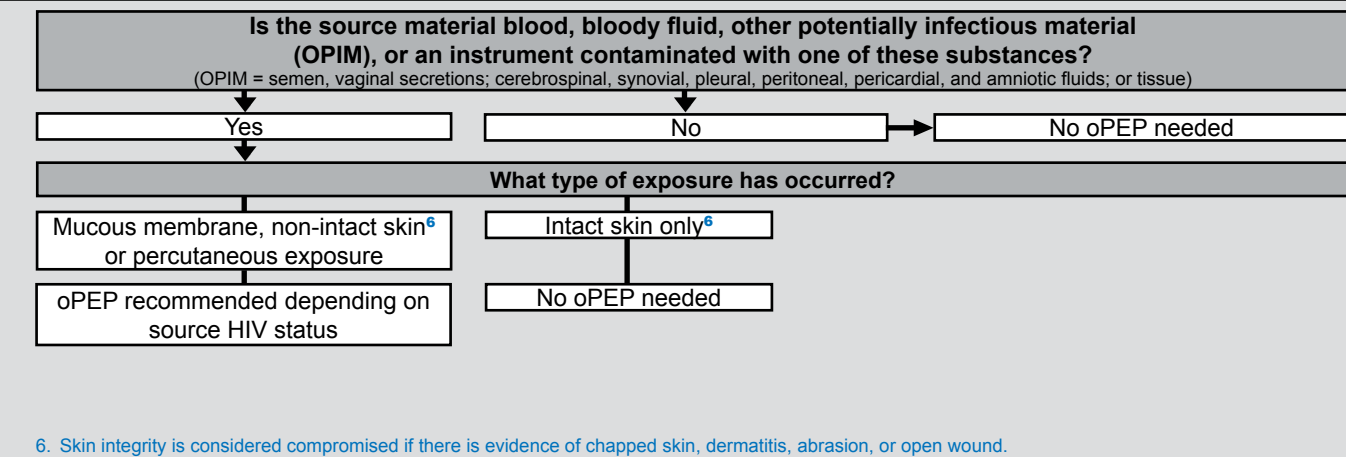
### Occupational Post-Exposure Prophylaxis (oPEP) for HIV

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. *MMWR*, 2005;54(RR-9). Available at: [www.aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf](http://www.aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf). Accessed: March 11, 2014.

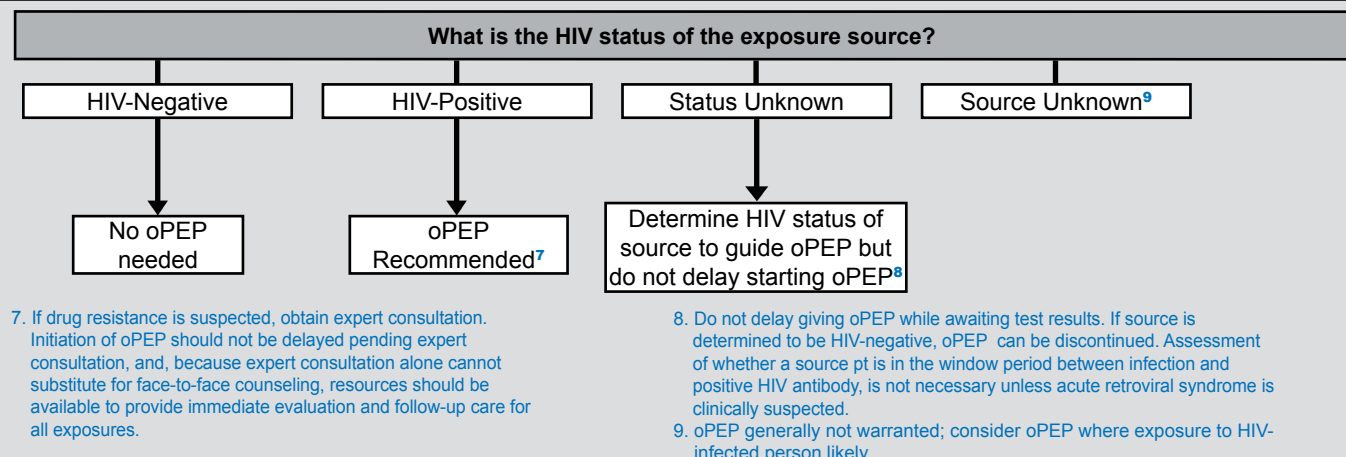
The Society for Healthcare Epidemiology of America. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. *Infection Control and Hospital Epidemiology*, 2013; 34(9) 875-892.

Available at: <http://www.jstor.org/stable/10.1086/672271>. Accessed: March 11, 2014.

#### Step 1: Evaluation of Exposure



#### Step 2: Determine the HIV Status of the Source



### Preferred and Alternative HIV Post-Exposure Prophylaxis Regimens (All regimens are for 28 days [4 weeks])

Please see the Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, (September 2013) at: <http://www.jstor.org/stable/10.1086/672271> and HRSA Nonoccupational Postexposure Prophylaxis, (January, 2011) at: [http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302\\_nonoccupational\\_peg.html](http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302_nonoccupational_peg.html) for guidelines regarding management of exposures. The clinician is encouraged to consult an expert in PEP management when choosing a regimen for an exposed pregnant woman or in cases of exposures to virus known or suspected to be resistant to one or more antiretroviral agents. PEPline is a National Clinicians' Post-Exposure Prophylaxis Hotline open from 9 a.m. - 2 a.m. EST, 7 days a week. They can be reached at: 888.448.4911. See: <http://nccc.ucsf.edu/clinician-consultation/post-exposure-prophylaxis-peg/> for additional information.

**NOTE:** Some pharmacies may not "break" their bottles of ARVs which typically come in a 30-day supply. Consider ordering a complete 30-day supply to assure PEP is started in a timely manner.

PREFERRED oPEP REGIMENS	ALTERNATIVE oPEP REGIMENS
Raltegravir (Isentress <sup>®</sup> ) 400 mg po twice daily <b>PLUS</b> Tenofovir/Emtricitabine 300/200 mg (Truvada <sup>®</sup> ) po once daily	For alternative oPEP regimens see current U.S. Public Health Service occupational postexposure prophylaxis guidelines at: <a href="http://www.jstor.org/stable/10.1086/672271">http://www.jstor.org/stable/10.1086/672271</a>
PREFERRED nPEP REGIMENS (HRSA GUIDELINES, JANUARY 2011)	
Lopinavir/Ritonavir (Kaletra <sup>®</sup> ) 400/100 mg po twice daily <b>PLUS</b> Tenofovir/Emtricitabine (Truvada <sup>®</sup> ) 300/200 mg po once daily	For alternative nPEP regimens see current HRSA non-occupational post-exposure prophylaxis guidelines (January 2011) at: <a href="http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302_nonoccupational_peg.html">http://hab.hrsa.gov/deliverhivaidscares/clinicalguide11/cg-302_nonoccupational_peg.html</a> or New York State Department of Health non-occupational post-exposure prophylaxis guidelines (July 2013) at: <a href="http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/">http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/</a>
OR	
Lopinavir/Ritonavir (Kaletra <sup>®</sup> ) 400/100 mg po twice daily <b>PLUS</b> Zidovudine/Lamivudine (Combivir <sup>®</sup> ) 300/150 mg po twice daily	
PREFERRED nPEP REGIMEN (NY STATE DEPARTMENT OF HEALTH, JULY 2013)	
Raltegravir (Isentress <sup>®</sup> ) 400 mg po twice daily <b>PLUS</b> Tenofovir/Emtricitabine 300/200 mg (Truvada <sup>®</sup> ) po once daily	

### Antiretrovirals Recommended for oPEP and nPEP (Dosage Forms and Important Points)

Refer to Appendix B of the Adult/Adolescent Antiretroviral Guidelines for a complete and updated source for antiretroviral medications to include: dosing, renal or hepatic insufficiency dosage adjustments, side effects, drug interactions, and warnings/contraindications.

<http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

DRUG	DOSAGE FORMS	IMPORTANT POINTS
Combivir <sup>®</sup> (Zidovudine/Lamivudine)	Zidovudine 300 mg/Lamivudine 150 mg tab	See individual components
Emtricitabine (Emtriva <sup>®</sup> )	200 mg cap, 10 mg/mL oral solution (soln)	<ul style="list-style-type: none"> <li>Take with or without food</li> <li>Abrupt withdrawal can cause chronic active HBV flares</li> <li>Adverse effects: generally well-tolerated, ↑ pigmentation of palms/soles (&gt; in black and Hispanic pts)</li> </ul>
Lamivudine (Epivir <sup>®</sup> )	150 mg, 300 mg tab, 10 mg/mL oral soln	<ul style="list-style-type: none"> <li>Take with or without food</li> <li>Abrupt withdrawal can cause chronic active HBV flares</li> <li>Adverse effects: generally well-tolerated</li> </ul>
Lopinavir/Ritonavir (Kaletra <sup>®</sup> )	Lopinavir 200 mg/Ritonavir 50 mg tab Lopinavir 100 mg/Ritonavir 25 mg tab Lopinavir (80 mg/mL)/Ritonavir (20 mg/mL) oral soln	<ul style="list-style-type: none"> <li>Swallow tabs whole; cannot be chewed, broken, or crushed</li> <li>May take tabs with or without food, soln should be taken with food</li> <li>Adverse effects: GI intolerance (nausea, vomiting, diarrhea); asthenia; ↑ ALT, aspartate transaminase (AST); prolonged PR, rare cases of 2<sup>nd</sup>/3<sup>rd</sup> degree AV block; prolonged QT interval, rare cases of torsade de pointes (causality not established)</li> </ul>
Raltegravir (Isentress <sup>®</sup> )	400 mg tab, 25 and 100 mg chewable tabs	<ul style="list-style-type: none"> <li>Take with or without food</li> <li>Adverse effects: diarrhea, nausea, headache, and pyrexia; ↑ ALT, AST, creatine phosphokinase; myopathy and rhabdomyolysis have been reported, rare severe skin reactions (SJS/TEN) and systemic HSR with rash, and constitutional symptoms +/- hepatitis</li> </ul>
Tenofovir (Viread <sup>®</sup> )	300, 150, 200, 250 mg tab, 40 mg/1g oral powder	<ul style="list-style-type: none"> <li>Take tabs with or without food; take powder with food</li> <li>Abrupt withdrawal can cause chronic active HBV flares</li> <li>Do not use for PEP in pts with estimated CrCL &lt; 60 mL/min</li> <li>Adverse effects: flatulence, headache, renal insufficiency, Fanconi Syndrome (rare), ↓ PO<sub>4</sub></li> </ul>
Truvada <sup>®</sup> (Tenofovir/Emtricitabine)	Tenofovir 300mg/Emtricitabine 200 mg tab	See individual components
Zidovudine (Retrovir <sup>®</sup> )	300 mg tab, 100 mg cap, 10 mg/mL oral soln	<ul style="list-style-type: none"> <li>Take with or without food (taking with food may ↓ nausea)</li> <li>Adverse effects: headache, nausea, ↑ pigmentation skin/nails, ↓ hemoglobin/hematocrit, ↓ white blood cell count, ↑ mean corpuscular volume (MCV), myopathy</li> </ul>