

VIRGINIA BOARD OF PHARMACY

Preventive Care

HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

Consistent with the manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

*Note: A pharmacy may create and use an electronic format for the PEP Patient Intake Form, PEP Assessment and Treatment Care Pathway, and PEP Patient Informational Handout, and PEP Provider Fax Notification if the information is identical to the forms included in this protocol.

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form (CONFIDENTIAL-Protected Health Information)

Date ____/____/____ Date of Birth ____/____/____ Age ____
 Legal Name _____ Preferred Name _____
 Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other ____
 Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other _____
 Street Address _____
 Phone () _____ Email Address _____
 Healthcare Provider Name _____ Phone () _____ Fax () _____
 Do you have health insurance? Yes / No Insurance Provider Name _____
 Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
2.	What was the date of the exposure?	____/____/____
3.	What was the approximate time of the exposure?	____:____ AM/PM
4.	Was your exposure due to unwanted physical contact or a sexual assault?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Tissue fluids <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Tears <input type="checkbox"/> Sweat <input type="checkbox"/> Other (please specify): _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? <input type="checkbox"/> persons with known HIV infection <input type="checkbox"/> men who have sex with men with unknown HIV status <input type="checkbox"/> persons who inject drugs <input type="checkbox"/> sex workers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify: _____	Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
13.	Are you seeing a provider for management of Hepatitis B?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when: _____ If no, would you like a vaccine today? Yes/No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
15.	Are you seeing a kidney specialist?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
16.	Are you currently pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
17.	Are you currently breast-feeding?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? <input type="checkbox"/> Orlistat (Alli®) <input type="checkbox"/> aspirin ≥ 325 mg <input type="checkbox"/> naproxen (Aleve®) <input type="checkbox"/> ibuprofen (Advil®) <input type="checkbox"/> antacids (Tums® or Rolaids®), <input type="checkbox"/> vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

Signature _____ Date _____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

Name: _____ Date of Birth: ___/___/_____ Today's Date: ___/___/_____

1. Is the patient less than 18 years old?		Notes:
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic	<input type="checkbox"/> No: Go to #2	
2. Was the patient a survivor of sexual assault?		Notes:
<input type="checkbox"/> Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**	<input type="checkbox"/> No: Go to #3	
3. Is the patient known to be HIV-positive?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	<input type="checkbox"/> No: Go to #4. Conduct 4 th generation HIV fingerstick test if available (optional).	
4. What time did the exposure occur?		Notes:
<input type="checkbox"/> >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.	<input type="checkbox"/> ≤72 hours ago: go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
<input type="checkbox"/> Yes: Go to #6	<input type="checkbox"/> No: Go to #7	
6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:		Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.
Please check any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Rectal secretions <input type="checkbox"/> Breast milk <input type="checkbox"/> Any body fluid that is visibly contaminated with blood If any boxes are checked, go to #9.	Please check any/all that apply (<i>Note: only applicable if not visibly contaminated with blood</i>): <input type="checkbox"/> Urine <input type="checkbox"/> Nasal Secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Sweat <input type="checkbox"/> Tears <input type="checkbox"/> None of the above Go to #7	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
<input type="checkbox"/> Yes: Go to #9	<input type="checkbox"/> No: Go to #8	

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

<p>8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</p>		<p>Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</p>
<p><input type="checkbox"/> Yes: Please check all that apply and go to #9:</p> <p><input type="checkbox"/> Was the source person known to be HIV-positive?</p> <p><input type="checkbox"/> Were there cuts/openings/sores/ulcers on the oral mucosa?</p> <p><input type="checkbox"/> Was blood present?</p> <p><input type="checkbox"/> Has this happened more than once without PEP treatment?</p> <p><input type="checkbox"/> None of the above</p>	<p><input type="checkbox"/> No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</p>	
<p>9. Does the patient have an established primary care provider for appropriate follow-up? –OR– Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</p>		<p>Notes: Connection to care is critical for future recommended follow-up.</p>
<p><input type="checkbox"/> Yes: Go to #10</p>	<p><input type="checkbox"/> No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</p>	
<p>10. Does the patient have history of known Hepatitis B infection (latent or active)?</p>		<p>Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</p>
<p><input type="checkbox"/> Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</p>	<p><input type="checkbox"/> No. Go to #11</p>	
<p>11. Has the patient received the full Hepatitis B vaccination series? <input type="checkbox"/> Yes <input type="checkbox"/> No Verify vaccine records or VIIS. Dates: _____</p>		
<p><input type="checkbox"/> Yes: Go to #13</p>	<p><input type="checkbox"/> No: Go to #12</p>	
<p>12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.</p> <p><input type="checkbox"/> Vaccine administered</p> <p>Lot: _____ Exp: _____ Signature: _____</p>		
<p>13. Does the patient have known chronic kidney disease or reduced renal function?</p>		<p>Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min</p>
<p><input type="checkbox"/> Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</p>	<p><input type="checkbox"/> No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</p>	

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Medication	Age/Weight	Dose	Duration	Notes
emtricitabine 200mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)	≥ 18 years	Once daily No refills	28 days	<ul style="list-style-type: none"> Dosing adjustments with renal dysfunction if CrCl <60 ml/min. Dolutegravir should not be used in pregnant women. If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then the “alternate regimens” per CDC guidelines should be referenced and used. Other FDA-approved regimens can be used if they become available. Formulation cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens. Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such. Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. “Pumping and dumping” may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.
PLUS				
raltegravir 400mg		Twice daily No refills		
OR				
dolutegravir 50mg		Once daily No refills		

COUNSELING POINTS (at minimum):

- Proper use of medication dosage, schedule, and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

- The importance and requirement of follow up testing for HIV, renal function , hepatic function , hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient’s primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature _____ Date ____/____/____

Patient Information

Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name: _____

Pharmacy Address: _____

Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Key Points

- You must start the medications within 72 hours of your exposure.
- Take every dose. If you miss a dose, take it as soon as you remember.
 - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking the medication without first asking your doctor or pharmacist.
- The most common side effects (if they do happen) are stomach upset. Taking the medication with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
 - HIV antigen/antibody 4th generation
 - Hepatitis B surface antigen and surface antibody
 - Hepatitis C antibody
 - Treponema pallidum antibody
 - Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider _____ (name), (____) _____ - _____ (FAX)

Your patient _____ (name) ____/____/____ (DOB) has been initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

This regimen was initiated on _____ (Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Emtricitabine/tenofovir disoproxil fumarate needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Etricitabine/tenofovir disoproxil fumarate and raltegravir are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with emtricitabine/tenofovir disoproxil fumarate.
- Emtricitabine/tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at 6 weeks after the initiation date for HIV PEP:

- HIV antigen/antibody (4th gen) test
- Hepatitis B surface antigen and surface antibody
- Hepatitis C antibody
- Comprehensive metabolic panel
- Treponema pallidum antibody as appropriate
- Pregnancy test as appropriate
- STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at 3 months after the initiation date for HIV PEP:

- HIV antigen/antibody (4th gen) test
- Hepatitis C antibody

If you have further questions, please contact the pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.