PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.

- STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:
  - Utilize the standardized PEP Patient Intake Form (pg. 2)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
  - Utilize the standardized PEP Patient Informational Handout (pg. 7)
  - Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST TRAINING/EDUCATION:
- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care
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)? □ Yes □ No □ 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? □ Yes □ No □ Not sure

5. Was the exposure through contact with any of the following body fluids? Select any/all that apply:
   □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):______________________________
   □ Yes □ No □ Not sure

6. Did you have vaginal or anal sexual intercourse without a condom? □ Yes □ No □ Not sure

7. Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner? □ Yes □ No □ 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? □ Yes □ No □ 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? □ Yes □ No □ Not sure

10. Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals?
   □ persons with known HIV infection
   □ men who have sex with men with unknown HIV status
   □ persons who inject drugs
   □ sex workers
   □ Yes □ No □ 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 □ No □ Not sure

Medical History:

12. Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)? □ Yes □ No □ Not sure

13. Are you seeing a provider for management of Hepatitis B? □ Yes □ No □ Not sure

14. Have you ever received immunization for Hepatitis B? If yes, indicate when:__________
   □ Yes □ No □ Not sure
   If no, would you like a vaccine today? Yes/No

15. Are you seeing a kidney specialist? □ Yes □ No □ Not sure

16. Are you currently pregnant? □ Yes □ No □ Not sure

17. Are you currently breast-feeding? □ Yes □ No □ Not sure

18. Do you take any of the following over-the-counter medications or herbal supplements?
   □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids
   (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium,
   zinc, or aluminum □ Yes □ No □ Not sure

19. Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: ____________________________________________ Yes □ No □ Not sure

Signature_________________________________________________________________________ Date_______________
# Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
## Assessment and Treatment Care Pathway
(Confidential-Protected Health Information)

**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.
- **Warning:** This type of exposure puts the patient at a high risk for HIV acquisition.

<table>
<thead>
<tr>
<th>Step</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Is the patient less than 13 years old?</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ 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</td>
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<td></td>
<td>☐ No: Go to #2</td>
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<tr>
<td>2.</td>
<td>Was the patient a survivor of sexual assault?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ 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.**</td>
<td>☐</td>
<td>☐</td>
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<td></td>
<td>☐ No: Go to #3</td>
<td>☐</td>
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<tr>
<td>3.</td>
<td>Is the patient known to be HIV-positive?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td>
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<td>4.</td>
<td>What time did the exposure occur?</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ &gt;72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td>
<td>☐</td>
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<td></td>
<td>☐ ≤72 hours ago: go to #5</td>
<td>☐</td>
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<tr>
<td>5.</td>
<td>Was the exposure from a source person known to be HIV-positive?</td>
<td>☐</td>
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<td></td>
<td>☐ Yes: Go to #6</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ No: Go to #7</td>
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<tr>
<td>6.</td>
<td>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:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Please check any/all that apply:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Blood</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Semen</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ Vaginal secretions</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ Rectal secretions</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ Breast milk</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ Any body fluid that is visibly contaminated with blood</td>
<td>☐</td>
<td>☐</td>
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<td></td>
<td>If any boxes are checked, go to #9.</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
<td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Urine</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Nasal secretions</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Saliva</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Sweat</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Tears</td>
<td>☐</td>
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<tr>
<td></td>
<td>☐ None of the above</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>7.</td>
<td>Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ Yes: Go to #9</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐ No: Go to #8</td>
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</tbody>
</table>
# Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

**Assessment and Treatment Care Pathway**

(Confidential-Protected Health Information)

<table>
<thead>
<tr>
<th>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?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes: Please check all that apply and go to #9:</td>
</tr>
<tr>
<td>☐ Was the source person known to be HIV-positive?</td>
</tr>
<tr>
<td>☐ Were there cuts/openings/sores/ulcers on the oral mucosa?</td>
</tr>
<tr>
<td>☐ Was blood present?</td>
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<tr>
<td>☐ Has this happened more than once without PEP treatment?</td>
</tr>
<tr>
<td>☐ None of the above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>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?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes: Go to #10</td>
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<table>
<thead>
<tr>
<th>10. Does the patient have history of known Hepatitis B infection (latent or active)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 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.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>11. Has the patient received the full Hepatitis B vaccination series? ☐ Yes ☐ No</th>
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</thead>
<tbody>
<tr>
<td>☐ Yes: Go to #13</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Vaccine administered Lot:_________ Exp:__________ Signature:_________________________________</td>
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<table>
<thead>
<tr>
<th>13. Does the patient have known chronic kidney disease or reduced renal function?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 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.</td>
</tr>
</tbody>
</table>

Notes: Connection to care is critical for future recommended follow-up.

Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.

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Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min
### RECOMMENDED REGIMEN:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days |                                                                                                                                     | - There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.  
- 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](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 Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days |                                                                                                                                     |                                                                                                                                      |

### COUNSELING POINTS:

- **Truvada®:**  
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.  
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.  
- **Isentress®:**  
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.  
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.  
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.  
- Discuss side-effects of “start-up syndrome” such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.  
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).  

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ 1-855-503-SAFE (7233).*

### 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___/___/_______
# PEP Prescription

Optional-May be used by pharmacy if desired

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Date of birth:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City/State/Zip Code:</td>
<td>Phone number:</td>
</tr>
</tbody>
</table>

- Verified DOB with valid photo ID

*Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication*

## Rx

- **Drug:** emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada)  
  **Sig:** Take one tablet by mouth once daily in combination with Isentress for 30 days  
  **Quantity:** #30  
  **Refills:** none

  **AND**

- **Drug:** raltegravir 400mg (Isentress)  
  **Sig:** Take one tablet by mouth twice daily in combination with Truvada for 30 days.  
  **Quantity:** #60  
  **Refills:** none

Written Date: ________________________________

Prescriber Name: ____________________________  
Prescriber Signature: ________________________

Pharmacy Address: ____________________________  
Pharmacy Phone: ____________________________

- or -

- Patient Referred
- Hepatitis B Vaccination administered:
  
  **Lot:** __________  
  **Expiration Date:** ______  
  **Dose:** _____ of 2 or 3 (circle one)

Notes: ____________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________
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 the medications and directions you have been prescribed, 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.

**Medications: You must start these within 72 hours of your exposure**
- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, AND
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

**Key Points**
- 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 either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don’t have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress 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.
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.
Dear Provider________________________________________ (name), (____) _____ - ______ (FAX)

Your patient ________________________(name) _____/_____/________  (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at ___________________________ Pharmacy.

This regimen consists of:
• Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
• Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

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:
• Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
• Truvada and Isentress 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 Truvada.
• Truvada 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 prescribing 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.