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. 2-3)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 4-6)

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)

Name_________________________________ Date of Birth______________ Age______ Today’s Date_______________

Health Care Provider’s Name___________________________________________________________________________

Do you have health insurance? Yes / No Name of Insurance Provider___________________________________________

Any allergies to Medications? Yes / No If yes, list them here _________________________________________________

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:______________ If no, would you like this 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®/Motrin®)
    □ 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_______________
Patient Name:  
Address:  
City/State/Zip Code:  
Phone number:  

☑ 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 fumurate 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 3

Notes:__________________________________________________________________________________  
__________________________________________________________________________________  
__________________________________________________________________________________  
__________________________________________________________________________________
Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)-Assessment and Treatment Care Pathway

<table>
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<tr>
<th>Name</th>
<th>Date of Birth</th>
<th>Today’s Date</th>
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1. **Is the patient less than 13 years old?**
   - 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.
   - No: Go to #2

   **Notes:** According to the CDC PEP treatment guidelines, Truvada® plus Isentress® is a preferred regimen for individuals 13 years and older.

2. **Is the patient known to be HIV-positive?**
   - Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.
   - No: Go to #3

   **Notes:**

3. **What time did the exposure occur?**
   - □ ≤72 hours ago: go to #4
   - □ >72 hours ago: PEP not recommended. Refer patient to local primary care provider, infectious disease specialist, or public health department.

   **Notes:** PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.

4. **Was the patient a survivor of sexual assault?**
   - Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #5) and then refer the patient to the emergency department for a sexual assault workup.**
   - No: Go to #5

   **Notes:**

5. **Was the exposure from a source person known to be HIV-positive?**
   - Yes: Go to #6
   - 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:**
   - Please check any/all that apply:
     - □ Blood
     - □ Semen
     - □ Vaginal secretions
     - □ Rectal secretions
     - □ Breast milk
     - □ Any body fluid that is visibly contaminated with blood

   **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.

   If any boxes are checked, go to #9.

   **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?**
   - Yes: Go to #9
   - No: Go to #8

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

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?**
   - Yes: Please check all that apply and go to #9:
     - □ Was the source person known to be HIV-positive?
     - □ Were there cuts/openings/sores/ulcers on the oral mucosa?
     - □ Was blood present?
     - □ Has this happened more than once without PEP treatment?
     - □ None of the above
   - No: Use clinical judgment. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.

   **Notes:** Consider calling the HIV PEP line (888) 448-4911 for guidance.
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?

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<tr>
<th>Yes: Go to #10</th>
<th>No: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</th>
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Notes: Connection to care is critical for future recommended follow-up.

10. Does the patient have history of known Hepatitis B infection (latent or active)?

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<tr>
<th>Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</th>
<th>No. Go to #11</th>
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Notes: Tenofovir disoproxil fumurate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.

11. Has the patient received the full Hepatitis B vaccination series? □ Yes □ No Verify vaccine records or AlertIIS. Dates:

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<tr>
<th>Yes: Go to #13</th>
<th>No: Go to #12</th>
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12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.

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<th>□ Vaccine administered</th>
<th>Lot:________ Exp:________ Signature:_________________________________</th>
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13. Does the patient have known chronic kidney disease or reduced renal function?

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<th>Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP.</th>
<th>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.</th>
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Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min

Recommended regimen:

**Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg)** one tablet by mouth daily for 30 days

PLUS

**Isentress® (raltegravir 400 mg)** one tablet by mouth twice daily for 30 days

Notes:

- 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.
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__________