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 855-115-0330, OAR 855-115-0335, **and this protocol** a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.
- The prescribing Pharmacist is responsible for all laboratory tests ordered, resulted and reporting as required.

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. 6)
- Utilize the standardized PEP Provider Fax (pg. 7)

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

REFERENCES

- **Utilize the standardized PEP Prescription Template *optional***
- **Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025**
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post-exposure Prophylaxis. Accessed February 14, 2023. https://stacks.cdc.gov/view/cdc/20711
- **Preventing HIV with PEP https://www.cdc.gov/hiv/prevention/pep.html**

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____

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.	Are you UNDER 13 years old?	□ Yes □ No
2.	Do you weigh LESS than 77 **pounds**?	□ Yes □ No □ Not sure
3.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
4.	What was the date of the exposure?	___/___/___
5.	What was the approximate time of the exposure?	___:___ *AM/PM*
6.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
7.	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
8.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
9.	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
10.	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
11.	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
12.	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
13.	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:

14.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
15.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
16.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
17.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
18.	Are you currently pregnant?	□ Yes □ No □ Not sure
19.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
20.	**Are you currently taking HIV PrEP?**	□ Yes □ No □ Not sure
21.	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
22.	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)

1) PEP Eligibility- Review Patient Intake Form #1 **and** #2

Is the patient < 13 years old[i]
Is the Patient <77 lbs[ii]

☐ **NO** → ☐ **YES** → Refer

2) CURRENT HIV STATUS and HIV TEST (HIV Ag/Ab test optional) Review Patient Intake form #14

☐ **NO** history of HIV
HIV Ag/Ab Test ☐ non-reactive ☐ decline

☐ **YES** has history of HIV → Refer
HIV Ag/Ab Test result ☐ reactive ☐ indeterminate[iii,iv,v] → Refer and Report

3) TIME OF EXPOSURE Review Patient Intake Form #4 **and** #5
-PEP is a time sensitive treatment with evidence supporting use **ideally within 24 hours, but no later than** 72 hours from time of exposure

☐ **≤72 hours ago**

☐ **>72 hours ago** → Refer to ER

4) SEXUAL ASSAULT SURVIVOR? Review Patient Intake Form #6
If the patient experienced a sexual assault, continue with the algorithm and then refer the patient to the emergency department for a sexual assault workup.**

☐ **NO**

☐ **YES** → Refer for Sexual Assault Evaluation

5) CONNECTION TO FOLLOW-UP CARE[iii,v]
Connection to care is critical for future recommended follow-up

-Primary Care Provider ☐ **YES**
-Directly Refer to Public Health Department ☐ **YES**

☐ **NO** → Refer to ER

6) HIV ACQUISITION RISK
Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

a) Source person is known to be HIV-positive?
Review Patient Intake Form #3

☐ **YES** → Go to b)

☐ **UNKNOWN** → Go to b)

☐ **NO** → Go to b)

Bodily Fluid Exposure Review Patient Intake Form #7 **and** #11

b) Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membranes, or non-intact skin, or percutaneous (needlestick) contact with the following body fluids?

Substantial-risk fluid exposure
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

Substantial risk fluid exposure <u>if contaminated with blood</u>
(*Note: only applicable if not visibly contaminated with blood*):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears

c) Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status? Review Patient Intake Form #6
-This type of exposure puts the patient at substantial risk for HIV acquisition

☐ **YES** → Go to #7

☐ **NO** → Go to d)

d) 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? Review Patient Intake Form #9 **and #**10

☐ **YES**: Please check all that apply
☐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 → Go to #7

☐ **NO**
- Risk of acquiring HIV is low.

-PEP may be offered regardless of HIV acquisition risk
If clinical determination is to prescribe PEP, → Go to #7

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

(CONFIDENTIAL-Protected Health Information)

7) Medical and Medication History

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.

Hepatitis B
Review Patient Intake Form #15, 16
- Truvada® (FTC/TDF) treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare
-Review the risks of hepatitis B exacerbation with PEP with the patient

Renal Function
Review Patient Intake Form #17
-Truvada® (FTC/TDF) requires renal dose adjustment when the CrCl <50ml/min

Pregnant or Breastfeeding
Review Patient Intake Form #18,19
- Pregnancy is not a contraindication to receiving PEP treatment

☐ **NO** ☐ **YES**

Taking HIV PrEP
Review Patient Intake Form #20

☐ **NO**

☐ **YES**
-Assess HIV PrEP Medication Adherence
-Missed Doses

☐ **NO** ☐ **YES**
Do not prescribe HIV PEP
Refer

History of known Hepatitis B infection (latent or active)?

☐ **NO**

☐ **YES** → Refer to ER

Confirmation of being fully vaccinated for hepatitis B via ALERT-IIS

☐ **NO**
-Offer vaccine if appropriate

☐ **YES**

-Chronic Kidney Disease
-Reduced Renal Function

☐ **NO**

☐ **YES** → Refer to ER

STEP 8: PRESCRIBE

- **Biktarvy ® (bictegravir (BIC) 50 mg / emtricitabine (FTC) 200mg / tenofovir alafenamide (TAF) 25 mg once daily for 30 days**
  -or-
- Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days **PLUS Tivicay® (dolutegravir 50 mg) once daily for 30 days**
  -or-
- **Descovy® (emtricitabine/tenofovir alafenamide (TAF) 200/25 mg one tablet by mouth daily for 30 days PLUS Tivicay® (dolutegravir 50 mg) once daily for 30 days**
  -or-
- **Tivicay® (dolutegravir 50 mg) once daily for 30 days PLUS tenofovir disoproxil fumarate (TDF) 300 mg *OR* tenofovir alafenamide (TAF) 25 mg once daily for 30 days**
- **Tivicay® (dolutegravir 50 mg) once daily for 30 days PLUS emtricitabine (FTC) 200 mg once daily *OR* lamivudine (3TC) 300 mg once daily for 30 days**

[i] According to the CDC PEP treatment guidelines **the regimens listed above are preferred for individuals 13 years and older**.

[ii] Truvada® (FTC/TDF) dosing is approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb)

[iii] Refer patient to local primary care provider, infectious disease specialist, or public health department.

[iv] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA

[v] County Health Department Directory
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Oregon AIDS Education and Training Center List of PEP Resources, PEP Navigation Services, STI and HIV testing and treatment sites and community organizations: https://www.oraetc.org/pepresource-list

Consider calling the HIV Warmline (888) 448- 4911 for guidance.

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

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Biktarvy ® (bictegravir (BIC) 50 mg / emtricitabine (FTC) 200 mg / tenofovir alafenamide (TAF) 25 mg once daily for 30 days

-or-

Tivicay® (dolutegravir 50 mg) one tablet by mouth once daily for 30 days

PLUS

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

-or

Descovy®(emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP.
- 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 **Biktarvy ®,** Tivicay®,Truvada® and **Descovy®** 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 outweighs 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® (emtricitabine/tenofovir disoproxil fumurate):
  - 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.
  - NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Tivicay® (dolutegravir):
  - Take the tablet once daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - Concomitant use with aluminum-magnesium antacids is contraindicated.
  - Tivicay® (dolutegravir) must be administered 2 hours before or 6 hours after other polyvalent cations, but can be administered at the same time as calcium or iron if taken with food.
  - Metformin coadministration can increase metformin concentrations. Monitor blood glucose and for metformin side effects

- **Biktarvy ® (bictegravir (BIC) 50mg / emtricitabine (FTC) 200mg / tenofovir alafenamide (TAF) 25mg**
  - **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.**
  - **Biktarvy ®must be administered 2 hours before or 6 hours after other polyvalent cations, but can be administered at the same time as calcium or iron if taken with food.**

- Both medications (Truvada® **plus** Tivicay® 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).
- **Inform HIV PrEP can reduce the risk of acquiring HIV if they will have repeat or continuing exposure to HIV after the end of the nPEP course. Create an immediate transition from nPEP to PrEP as a recommendation for eligible populations.**

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

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*Oregon licensed pharmacists are mandatory reporters of child abuse (ORS Chapter 419B). Pharmacists should also report elder abuse and vulnerable adult abuse. Reports must be made to the 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 HIV RNA or 4th generation HIV Antigen/Antibody, Hepatitis B serology, Hepatitis C antibody, SCr, AST/ALT, Syphilis, Chlamydia and Gonorrhea testing and pregnancy.
- The pharmacist will provide a written individualized care plan to each patient.
- The pharmacist should attempt to contact the patient within the first 24 hours to assess medication tolerability and adherence and to advocate for appropriate provider follow-up 4 to 6 weeks and 12 weeks after exposure for laboratory testing.

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

Pharmacy Name: _____Pharmacist 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 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

- **Biktarvy® (bictegravir (BIC) 50 mg / emtricitabine (FTC) 200 mg / tenofovir alafenamide (TAF) 25 mg once daily for 30 days OR**
- Truvada® (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **OR**
- **Descovy® (emtricitabine/tenofovir alafenamide (TAF) 200/25 mg**
  Take 1 tablet by mouth daily for 30 days
- **AND**
- Tivicay® (dolutegravir) 50 mg - take 1 tablet by mouth once 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 healthcare provider or pharmacist.
- Truvada®, Tivicay®, and **Descovy®** and **Biktarvy®** are well tolerated by most people. The most common side effects (if they do happen) are stomach upset. Taking **Biktarvy®**, **or** Truvada®, **Descovy® and** Tivicay® with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Acetaminophen is the preferred over-the-counter pain medication. Avoid medications such as 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 healthcare provider (or public health office if you do not have a primary healthcare provider) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 4-6 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 RNA or HIV antigen/antibody
   - ☐ Kidney function - Serum creatinine (SCr)
   - ☐ Liver function- Alanine transaminase (ALT) and aspartate aminotransferase (AST)
   - ☐ Sexually transmitted diseases- Syphilis, Chlamydia and Gonorrhea
   - ☐ Pregnancy
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 **or pharmacist** about starting Pre-Exposure Prophylaxis (PrEP) after finishing PEP.

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

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

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

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

This regimen consists of:

- **Biktarvy ® (bictegravir (BIC) 50 mg / emtricitabine (FTC) 200 mg / tenofovir alafenamide (TAF) 25mg once daily for 30 days OR**
- **Tivicay® (dolutegravir) 50 mg - take 1 tablet by mouth once daily for 30 days, AND**
- Truvada® (emtricitabine/tenofovir disoproxil) 200/300 mg tablets - one tab by mouth daily for 30 days OR **AND**
- **Descovy® (emtricitabine/tenofovir alafenamide (TAF) 200/25 mg**

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®, Tivicay®, and **Biktarvy®** are 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® and Biktarvy® **are** ~~is~~ a first line options 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 after the initiation of HIV PEP:

Test	Baseline	4-6 weeks after exposure	3 months after exposure
HIV RNA or HIV antigen/antibody	x	x	x
Hepatitis B serology	x	-	-
Hepatitis C antibody	x	-	-
Serum creatinine	x	x	-
Alanine transaminase, aspartate aminotransferase	x	x	-
For Sexual Exposure Only			
Syphilis, gonorrhea, chlamydia testing	x	x	-
Pregnancy	x	x	-

Exposed person should be tested again at 6 months for hepatitis B serology and hepatitis C antibody, if they are susceptible to hepatitis B and hepatitis C, respectively. Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status at 6 months.

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 https://cdc.gov/hiv/prevention/pep.html?CDC_AAref_Val=https://cdc.gov/hiv/basics/pep.html%20cdc.gov/hiv/basics/pep.html.

PEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

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

Rx

- Drug: bictegravir (BIC) 50 mg / emtricitabine (FTC) 200mg / tenofovir alafenamide (TAF) 25 mg (Biktarvy®)
  Sig: Take one tablet by mouth once daily for 30 days
  Quantity: #30
  Refills: none

-OR-

- 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: dolutegravir 50mg (Tivicay®)
  Sig: Take one tablet by mouth once daily in combination with Truvada for 30 days.
  Quantity: #30
  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:_____
_____
_____
_____