PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per <u>ORS 689.645</u>, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in <u>OAR 855-115-0330</u> and <u>OAR 855-115-0335</u>, 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 Prescription Template optional (pg. 6)
- 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

REFERENCES

- Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection drug use, or Other Non-occupational Exposure to HIV—United States, 2016. Accessed February 14, 2023. https://stacks.cdc.gov/view/cdc/38856
- 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
- PEP | HIV Basics | HIV/AIDS | CDC. Published July 11, 2022. Accessed February 14, 2023. https://www.cdc.gov/hiv/basics/pep.html

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

(CONFIDENTIAL-Protected Health Information)

	/		// Age
	Name	Name	
	ssigned at Birth (circle) M / F		n (circle) M / F / Other
	ouns (circle) She/Her/Hers, He/Him/His, They/Ti t Address		
Phon		Email Address	
	chcare Provider Name	Phone ()	_Fax ()
	ou have health insurance? Yes / No	Insurance Provider Name	
	allergies to medications? Yes / No	If yes, please list	
-	ground Information:		
1.	Are you UNDER 13 years old?		□ Yes □ No
2.	Do you weigh LESS than 77 pounds (lbs)?		☐ Yes ☐ No ☐ Not sure
3.	Do you think you were exposed to Human Imm	unodeficiency Virus (HIV)?	☐ Yes ☐ No ☐ Not sure
4.	What was the date of the exposure?		
5.	What was the approximate time of the exposur	e?	:AM/PM
6.	Was your exposure due to unwanted physical c	ontact or a sexual assault?	☐ Yes ☐ No ☐ Not sure
7.	Was the exposure through contact with any of	the following body fluids? Select any/a	II □ Yes □ No □ Not sure
	that apply:		
	□ Blood □ Tissue fluids □ Semen □ Vaginal secre	etions 🗆 Saliva 🗆 Tears 🗆 Sweat 🗆 Other	r
	(please specify):		
8.	Did you have vaginal or anal sexual intercourse		☐ Yes ☐ No ☐ Not sure
9.	Did you have oral sex without a condom with vi	sible blood in or on the genitals or	☐ Yes ☐ No ☐ Not sure
10	mouth of your partner?	ration alian au marcana manana af the	- Ves = Ne = Net sure
10.	Did you have oral sex without a condom with b	roken skin or mucous membrane of the	e
11	genitals or oral cavity of your partner?	o skin a noodla or another instrumen	nt
11.	Were you exposed to body fluids via injury to the or object that broke the skin?	ie skiii, a needie, or another instrumen	it Lifes Lino Linot sure
12.	Did you come into contact with blood, semen, v	vaginal secretions, or other hody fluids	of
12.	one of the following individuals?	aginal secretions, or other body halds	or les line inot sale
	persons with known HIV infection		
	men who have sex with men with unknown H	IV status	
	persons who inject drugs	Status	
	□sex workers		
13.	Did you have another encounter that is not incl	uded above that could have exposed	Yes □ No □ Not sure
	you to high risk body fluids? Please specify:	·	
Medi	cal History:		
14.	Have you ever been diagnosed with Human Imi	nunodeficiency Virus (HIV)?	☐ Yes ☐ No ☐ Not sure
15.	Are you seeing a provider for management of H	epatitis B?	☐ Yes ☐ No ☐ Not sure
16.	Have you ever received immunization for Hepa	itis B? If yes, indicate when:	☐ Yes ☐ No ☐ Not sure
	If no, would you like a vaccine today? Yes/No		_
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.	Do you take any of the following over-the-coun	ter medications or herbal supplements	s?
	□ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen	(Aleve $^{\circ}$) \square ibuprofen (Advil $^{\circ}$) \square antació	ds
	(Tums® or Rolaids®), □ vitamins or multivitamin	s containing iron, calcium, magnesium	,
	zinc, or aluminum		
21.	Do you have any other medical problems or tak		☐ Yes ☐ No ☐ Not sure
	supplements? If yes, list them here:		_
			_
Signa	A.u.a		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, 2								
	itient < 13 years old ⁱ itient <77 lbs ⁱⁱ	□NO	□YES Refer					
	ENT HIV STATUS and HIV TEST	(HIV Ag/Ab test optional)	Review Patient Intake form #14					
	story of HIV	_	☐ YES has history of HIV					
	Ab Test □ non-reactive □ declin	e	HIV Ag/Ab Test result □ reactive □ indeterminate iii,iv,v Refer and Report					
	3) TIME OF EXPOSURE Review Patient Intake Form #4, 5 -PEP is a time sensitive treatment with evidence supporting use 72 hours from time of exposure							
□ ≤72 hc		1	□ >72 hours ago Refer to ER					
	AL ASSAULT SURVIVOR? Review	/ Patient Intake Form #6						
If the pa	tient experienced a sexual assau		thm and then refer the patient to the emergency department for a sexual					
	vorkup.**		1=:					
□NO		1	□ YES Refer for Sexual Assault Evaluation					
	IECTION TO FOLLOW-UP CARE III ion to care is critical for future r							
	Care Provider	□ YES ■	□ NO					
-Directly	Refer to Public Health Departm	nent 🗆 YES 👢	Refer to ER					
6) HIV A	CQUISITION RISK		,					
Consider	r calling the HIV Warmline (888)		nclear					
a)	Source person is known to be Review Patient Intake Form #3	•						
	□YES	□UNKNOWN	□NO					
	Go to b)	Go to b)	Go to b)					
	Bodily Fluid Exposure Review	Patient Intake Form #7, #11	<u> </u>					
b)			, mouth, other mucous membranes, or non-intact skin, or percutaneous					
	(needlestick) contact with the		•					
	Substantial-risk fluid exposur	e	Substantial risk fluid exposure if contaminated with blood					
	□Blood	-	(Note: only applicable if not visibly contaminated with blood):					
	□Semen		□Urine					
	□Vaginal secretions		□Nasal Secretions					
	☐Rectal secretions		□Saliva					
	☐Breast milk		□Sweat					
	☐Any body fluid that is visibl	y contaminated with blood	□Tears					
c)	Did the patient have receptive	e/insertive anal/vaginal int	ercourse without a condom with a partner of known or unknown HIV					
	status? Review Patient Intake							
	-This type of exposure puts the	e patient at substantial risk						
	☐ YES Go to #7		□ NO Go to d)					
d)			nout a condom with mouth to vagina, anus, or penis (with or without n HIV status? Review Patient Intake Form # 9,10					
	☐ YES : Please check all that ap		□NO					
	☐Was the source person know	vn to be HIV-positive?	- Risk of acquiring HIV is low.					
	☐Were there cuts/openings/s	ores/ulcers on the oral	, , , , , , , , , , , , , , , , , ,					
	mucosa?		-PEP may be offered regardless of HIV acquisition risk If clinical determination is to prescribe PEP,					
	□Was blood present?		il clinical determination is to prescribe FEF,					
	☐ Has this happened more that	n once without PEP						
	treatment? □None of the above	Go to #7	Go to #7					
	cal and Medication History							
	Patient <u>must be warm referred</u> to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist							
must no	tify both the provider and patie	nt.						

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

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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		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		
•		-Chronic Kidney Disease -Reduced Renal Function		□NO	□ YES	
□ NO □ YES Refer to ER	□ NO -Offer vaccine if appropriate	□ YES	□NO	☐ YES Refer to ER	,	Ļ
Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days PLUS Isentress® (raltegravir400 mg) one tablet by mouth twice daily for 30 days					30 days PLUS	
 or- Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days PLUS Tivicay® (dolutegravir 50mg) once daily for 30 days 						30 days PLUS

ⁱAccording to the CDC PEP treatment guidelines, Truvada® (FTC/TDF) plus Isentress®(raltegravir) or Tivicay® (dolutegravir) is a preferred regimen for individuals 13 years and older.

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.

RECOMMENDED REGIMEN:

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

PLUS

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

-or-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.
- 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 Tivicay® or 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 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.

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

^v County Health Department Directory

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

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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.
 - o Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
 - o 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.
 - o 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
- Isentress® (raltegravir)
 - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
 - o Isentress® (raltegravir) must be administered 2 hours before or 6 hours after other polyvalent cations.
 - o Concomitant use is contraindicated with aluminum-hydroxide antacids
 - o Calcium carbonate: no dose adjustment or separation is necessary
- Both medications (Truvada® <u>plus</u> Tivicay® or Isentress®) 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 (<u>ORS Chapter 419B</u>). 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 will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

PEP Prescription

Optional-May be used by pharmacy if desired

atient Name:	Date of birth:				
Address:					
City/State/Zip Code:	Phone number:				
ote: RPh must refer patient if exposure c	occurred >72 hours prior to initiation of medication				
XX					
_	fovir disoproxil fumarate 300 mg (Truvada®)				
Sig: Take one tablet by mouth one Quantity: #30	ce daily in combination with Isentress for 30 days				
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					
	-OR-				
Drug: raltegravir 400mg (Isentress®)					
	ice daily in combination with Truvada for 30 days.				
Quantity: #60 Refills: none					
Remis: none					
ritten Date:					
escriber Name:	Prescriber Signature:				
armacy Address:	Pharmacy Phone:				
-or-					
Patient Referred					
Hepatitis B Vaccination administered:					
Lot:Expiration Date:	Dose: of 2 or 3 (circle one)				

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

- Truvada® (emtricitabine/tenofovir disoproxil) 200 mg/300 mg take 1 tablet by mouth daily for 30 days, AND
- Tivicay® (dolutegravir) 50mg take 1 tablet by mouth once daily for 30 days, OR
- 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.
 - o 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 Isentress® are well tolerated by most people. The most common side effects (if they do happen) are stomach upset. Taking Truvada®, Tivicay®, and Isentress® 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.

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 about starting Pre-Exposure Prophylaxis (PrEP) after finishing PEP.

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

Pharmacy Name:	Pha	rmacist	Name:				
Pharmacy Address:							
Pharmacy Phone:	Pharmacy	/ Fax:					
Dear Provider			(name), ()		(FAX)	
Your patient	(name)	/	/	(DOB) has	been pre	scribed HIV Post-	
Exposure Prophylaxis (PEP) at			Phar	macy.			
This regimen consists of:							
 Truvada® (emtricitabine/tenofov 	ir disoproxil) 20	0/300n	ng tablets -	one tab by i	mouth da	ily for 30 days AN	<u>D</u>
 Tivicay® (dolutegravir) 50mg - tak 	ke 1 tablet by m	outh o	nce daily fo	or 30 days, <u>O</u>	<u>R</u>		
 Isentress[®] (raltegravir) 400mg tal 	blets - one tab k	y mou	th twice da	ily for 30 day	ys.		
This regimen was initiated on			(Data)				

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 Isentress® 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® 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 after the initiation of HIV PEP:

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

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 cdc.gov/hiv/basics/pep.html.