

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](#) and [OAR 855-115-0335](#), 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>

ORAL Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Patient Information

Date ____/____/____ Date of Birth ____/____/____ Age ____

Name on Documents _____ Name _____

Sex Assigned at Birth (circle) M / F / Intersex Gender: _____ Are you transgender? (circle) Y/N/ _____

Pronouns: She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, _____

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: These questions are highly confidential and help the pharmacist to determine if ORAL PrEP may benefit you, be safe for you, and what lab screenings are recommended before starting or continuing on PrEP.

Section 1: Reason for HIV Pre-Exposure Prophylaxis (PrEP) and Eligibility

You do not have to indicate reason; please review and answer the question at the bottom of this box:	
<ul style="list-style-type: none"> ▪ I want to start PrEP ▪ I want to keep taking PrEP ▪ I had sex in the past 6 months ▪ I do not always use condoms when I have sex ▪ I had gonorrhea, chlamydia, or syphilis in the past 6 months 	<ul style="list-style-type: none"> ▪ I have had sex with someone living with HIV ▪ I have had sex with one or more partners and did not know their HIV status ▪ I injected drugs in the past 6 months ▪ I shared injection equipment (any)
1a. Is your answer YES to one of the above statements?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
1b. Are you UNDER 13 years old?	<input type="checkbox"/> Yes <input type="checkbox"/> No
1c. Do you weigh LESS than 77 pounds (35 kg)?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Section 2: HIV Testing, PrEP, and HIV Post-Exposure Prophylaxis (PEP) Histories; Acute HIV Symptom Review

2a. Have you ever had a positive, reactive, detected, or indeterminate test for HIV?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2b. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2c. Are you taking PrEP now or in the past? <ul style="list-style-type: none"> • If now, which PrEP medicine? _____. Skip question 2d and continue to question 2e. • If in the past, what was your reason for stopping? _____ 	<input type="checkbox"/> Yes <input type="checkbox"/> No
2d. Are you currently finishing a course of PEP after a possible HIV exposure?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2e. When was your last sex, injection drug use, or other possible exposure to HIV?	<input type="checkbox"/> Less than 72 hours (3 days) ago <input type="checkbox"/> More than 72 hours (3 days), but less than 4 weeks ago <input type="checkbox"/> More than 4 weeks ago

ORAL Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Section 3: Brief Medical History to Determine Which PrEP Medication May Be Best for You

3a. Have you been told you have kidney disease (e.g. kidney failure, poor kidney function)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3b. Have you been told you have a bone disease (e.g. osteoporosis, osteopenia, low bone mineral density, etc.?)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3c. Have you ever had Hepatitis B infection? --Have you been vaccinated for Hepatitis B? If Yes, Date(s): #1 ___/___/___ #2 ___/___/___ #3 ___/___/___ If No, do you want to start the Hepatitis B vaccination today?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure <input type="checkbox"/> Yes <input type="checkbox"/> No
3d. Are you pregnant, breastfeeding or planning to become pregnant? --If no, what are you using to prevent pregnancy? _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply
3e. Please list the names of other prescriptions (medicines), over-the-counter, herbal, or supplement products that you take so that the pharmacist can check for drug interactions with PrEP. Please note doses and use of any non-steroidal anti-inflammatory medicines (NSAIDs): ibuprofen (Advil/Motrin), naproxen (Aleve), meloxicam, celecoxib, diclofenac and any estradiol containing gender-affirming hormone medicines: _____ _____ _____ _____	
3f. Please list any other questions or medical concerns you would like to the pharmacist to know: 	

Section 4: What to Expect on Oral PrEP

The biggest risks of PrEP are:

1. Starting PrEP when you do not know that HIV is already there **and**
2. Staying on PrEP after contracting HIV. PrEP medicines are also used to *treat* HIV, but it's not full treatment. If someone starts the PrEP medicine while living with HIV -or- contracts HIV while taking PrEP, then the medicines in PrEP might not work for treatment.

Please be aware that:

1. HIV testing must be done every 3 months while taking PrEP. The pharmacist must document a negative HIV test result within the last 7 days before prescribing PrEP. If that is the only lab result available, then the pharmacist can only prescribe up to a 30-day supply until other labs are done. When all needed lab results are given to the pharmacist, then the pharmacist may be able to prescribe up to a 90-day supply each time.
2. Screenings for gonorrhea, chlamydia, and syphilis must be done at least every 6 months while taking PrEP. Undiagnosed sexually transmitted infections (STIs) may increase the risk of contracting HIV, even while you are taking PrEP, and PrEP does NOT protect against other STIs. Screening for gonorrhea and chlamydia must be done at each possible site of exposure via urine (genital) and swab (throat and rectum) collections.
3. Missing doses of PrEP increases the risk of contracting HIV. PrEP works the best when taken AS DIRECTED by the pharmacist. Please talk to your pharmacist if you are having trouble taking your PrEP and/or getting labs done.

Patient Signature: _____ **Date:** _____

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION					
1) PrEP INDICATION AND ELIGIBILITY - Review Patient Intake Form Questions #1a, 1b & 1c					
Is the patient < 13 years old ⁱ Is the Patient < 77 lbs ⁱⁱ		↓		<input type="checkbox"/> NO <input type="checkbox"/> YES	
Refer →					
2a) CURRENT HIV STATUS - Review Patient Intake Form #2a and HIV test results					
<input type="checkbox"/> NO history of HIV		<input type="checkbox"/> YES has history of HIV			
Refer →					
2b) HIV TEST - HIV Ag/Ab Test result* <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive *HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing - HIV RNA test result: <input type="checkbox"/> detected <input type="checkbox"/> indeterminate <input type="checkbox"/> not detected <input type="checkbox"/> result pending <input type="checkbox"/> none May order HIV RNA at initial intake (preferred) and as appropriate thereafter					
<input type="checkbox"/> NO current HIV HIV Ag/Ab Test non-reactive HIV RNA Test not detected		<input type="checkbox"/> YES possibly living with HIV HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)			
Refer and Report →					
3) ASSESS FOR POSSIBLE HIV ACQUISITION WITHIN THE PAST 4 WEEKS -Review Patient Intake Form #2b, 2c, 2d, and 2e •Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms. •Could have acute HIV with negative screening HIV Ag/Ab result -Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear					
Time of last potential exposure:	<input type="checkbox"/> ≤ 72 hours		<input type="checkbox"/> >72 hours to ≤ 4 weeks		<input type="checkbox"/> > 4 weeks
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) PEP Protocol →		<input type="checkbox"/> NO symptoms -Eligible for up to a 30-day supply of PrEP -Order HIV RNA test now -Counsel on acute retroviral syndrome symptoms	<input type="checkbox"/> YES symptoms (Communication Example B)	Refer →
4) MEDICAL and MEDICATION HISTORY - Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f					
Kidney Disease - Review Patient Intake form #3a		Bone Mineral Density - Review Patient Intake form #3b		Hepatitis B Status - Review Patient Intake Form #3c •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabine 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.	
<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> YES <input type="checkbox"/> NO		Pregnancy - Review Patient Intake form #3d	
Refer →		Refer →		Refer PRN →	
↓		↓		↓	
Hepatitis B History		Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS		Medication - Review Patient Intake form # 3e, 3f	
Refer →		<input type="checkbox"/> YES		<input type="checkbox"/> NO -Offer Hep B Vaccine series. -Order Hep B Surface Antigen (see Table 1)	
↓		↓		↓	
↓		↓		↓	

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

5) LABORATORY RESULTS- See Appendix A for detailed information on labs	
-Hepatitis B Vaccine series <input type="checkbox"/> completed or -Hepatitis B serologies resulted: <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet -Serum creatinine <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet -Syphilis/Treponemal antibody <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet -Gonorrhea/Chlamydia <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet Are all required Baseline labs resulted (Tables 2 and 3 below)? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
6) DETERMINE DURATION OF PrEP PRESCRIPTION	
-Required BASELINE labs resulted? <input type="checkbox"/> YES <input type="checkbox"/> NO -Was last possible exposure to HIV > 4 weeks ago (Patient intake Form #2e, Step 3 above)? <input type="checkbox"/> YES <input type="checkbox"/> NO	
If YES , - RPH may prescribe PrEP for up to a 90- day supply	If NO , - RPH may prescribe PrEP for up to a 30-day supply - Patient needs to complete all required labs within 30 days by the next refill

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

ALGORITHM B: PrEP CONTINUATION									
1) HIV TEST HIV Ag/Ab Test result* <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive *HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing HIV RNA test result <input type="checkbox"/> detected <input type="checkbox"/> indeterminate <input type="checkbox"/> not detected <input type="checkbox"/> result pending <input type="checkbox"/> none May order HIV RNA as appropriate									
HIV Ag/Ab Test non-reactive HIV RNA Test not detected <div style="text-align: center;"></div>				HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)				<div style="border: 2px solid red; padding: 5px; color: white; font-weight: bold;">Refer & Report</div>	
2) ASSESS FOR POSSIBLE ACUTE HIV INFECTION WITHIN THE PAST 4 WEEKS Review Patient Intake form #2b, 2c, 2d, 2e •Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms. •Could have acute HIV with negative screening HIV Ag/Ab result -Consider calling the HIV Warmline (888) 448- 4911 for guidance									
<input type="checkbox"/> No symptoms <div style="text-align: center;"></div>				<input type="checkbox"/> Symptoms -Eligible for PrEP for up to a 30-day supply. -Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription -Counsel on acute retroviral syndrome -May refer (See Communication Example C)				<div style="border: 2px solid yellow; padding: 5px; color: black; font-weight: bold;">Refer PRN</div>	
3) MEDICAL and MEDICATION HISTORY - Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f									
Kidney Disease - Review Patient Intake form #3a		Bone Mineral Density - Review Patient Intake form #3b		Hepatitis B Status Review Patient Intake Form #3c, 3d -Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection. •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabine 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		Pregnancy Review Patient Intake form #3e	Medication Review Patient Intake form # 3f		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Hepatitis B History <input type="checkbox"/> YES	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS <input type="checkbox"/> YES	Pregnancy and breastfeeding are not contraindications for PrEP.	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.		
<div style="border: 2px solid red; padding: 5px; color: white; font-weight: bold;">Refer</div>		<div style="border: 2px solid red; padding: 5px; color: white; font-weight: bold;">Refer</div>		<div style="border: 2px solid red; padding: 5px; color: white; font-weight: bold;">Refer</div>		<div style="border: 2px solid yellow; padding: 5px; color: black; font-weight: bold;">Refer PRN</div>			
4) LABORATORY RESULTS- See Appendix B for detailed information on labs -See Table 1: REQUIRED PrEP Labs -Serum creatinine <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet -Syphilis/Treponemal antibody <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet -Gonorrhea/Chlamydia <input type="checkbox"/> resulted, ok for protocol <input type="checkbox"/> resulted, needs referral <input type="checkbox"/> no result yet - Required PrEP Continuation labs resulted ? <input type="checkbox"/> YES <input type="checkbox"/> NO									
5) DETERMINE DURATION OF PrEP PRESCRIPTION -Required BASELINE labs resulted? <input type="checkbox"/> YES <input type="checkbox"/> NO									
If YES , - RPH may prescribe PrEP for up to a 90- day supply				If NO , - RPH may prescribe PrEP for up to a 30-day supply - Patient needs to complete all required labs within 30 days by the next refill					

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMENS:

Note: There are other FDA-Approved medications available and may be other dosing strategies for PrEP. Daily dosing of emtricitabine / tenofovir DF (Truvada®) and emtricitabine / tenofovir alafenamide (Descovy®) are the only regimens permitted for pharmacist prescribing at this time.

<p>Emtricitabine/Tenofovir DF (F/TDF; Truvada®):</p> <p>Dose: 200/300 mg once daily</p> <p>FDA-Approved for: all HIV exposure risk indications</p> <p>Preferred if: pregnancy/breastfeeding, vaginal exposure risks, substance use risks</p> <p>Not preferred if: concomitant nephrotoxic medications, or risks for/known renal insufficiency or osteopenia/osteoporosis</p> <p>Cost: available as a generic, lower-cost option</p>	<p>Emtricitabine/Tenofovir alafenamide(F/TAF; Descovy®):</p> <p>Dose: 200/25 mg once daily</p> <p>FDA-Approved for: use by men and transgender women only Not recommended for: HIV risk via vaginal sex or if injection substance use is the only HIV risk</p> <p>Preferred if: renal insufficiency, risk of renal insufficiency (e.g. uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for men or transgender women ONLY</p> <p>Cost: no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card</p>
---	---

COMMUNICATION EXAMPLES:

<p>Example A Reactive, positive, indeterminate, -or- detected result for:</p> <p>HIV Ag/Ab -or- HIV RNA</p>	<p>Your HIV test is [reactive, positive, -or- indeterminate]. This is not a diagnosis of HIV infection, but you do need further testing to confirm if this is a true result. Do you want to go to your Primary Care Provider, urgent care clinic, county health department, or an HIV specialist for further evaluation? It is important that you STOP taking PrEP now as it is an incomplete treatment for HIV and can lead to drug resistance in the future. Until you know your HIV test results/status, please use condoms during sex and/or use sterile injection equipment, not share with others. You may start PrEP again with a PrEP provider if it is determined that this was a false result and you do NOT have an HIV infection. I can help you make an appointment for further evaluation.</p>
<p>Example B Concerns for acute HIV infection NOT on PrEP</p>	<p>Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of a recent HIV infection. These symptoms are also general and could be related to the flu, COVID19, or another viral illness. I would like to recheck the regular HIV screening test and add another test that looks directly for the virus before we can START PrEP. These tests should be done at 2 to 4 weeks after your possible exposure. I cannot prescribe PrEP today, but we can get you started once we have these other lab results. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. They could also start you on PrEP if they decide it's appropriate to start now. Please let me know if you want a referral and/or would like me to refer you to a community organization¹ that can help link you to care and evaluation.</p>

Continued on next page →

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<p>Example B Concerns for acute HIV infection ON PrEP</p>	<p>Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of recent HIV infection. These symptoms are also very general and could be related to the flu, COVID19, or another viral illness. I would like to screen for HIV and add another test that looks directly for the virus. These should be done at 2 to 4 weeks after your possible exposure. While we wait for those lab results, I can prescribe up to a 30-day supply for this refill.</p> <p>You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. Please let me know if you want a referral and/or would like me to refer you to a community organization¹ that can help link you to care and evaluation.</p>
<p>Example D Reactive, positive, -or- indeterminate result for: Gonorrhea -or- Chlamydia -or- Syphilis</p>	<p>There were [reactive, positive, -or- indeterminate] results for [gonorrhea, chlamydia, and/or syphilis]. This is not a diagnosis of [gonorrhea, chlamydia, and/or syphilis], but you need further evaluation and possibly testing to confirm if this is a true result. Please keep taking your PrEP, do not stop PrEP. Please use condoms during sexual activity until you have been evaluated and/or treated by a clinical provider. I can help you make an appointment for further evaluation/treatment to a Primary Care Provider, urgent care clinic, or county health department.</p>

Table 1: PrEP Laboratory Requirements
REQUIRED:

Lab Data	BASELINE	In 1 month	Every 3 months	Every 6 months	Every 12 months
HIV Ag/Ab 4th generation test	X Required within 7 days before the start	X If first prescription is for 30 days	X Within 7 days before each new prescription		
HIV RNA¹	X		X		
Hepatitis B -Review vaccine Status and serologies	X				
Chlamydia Screening	X		X MSM/TGW	X	
Gonorrhea Screening	X		X MSM/TGW	X	
Syphilis Screening	X		X MSM/TGW	X	
SCr and calculated creatinine clearance	X			X If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start	X
OPTIONAL:					
Hepatitis C Ab *	X MSM/TGW, PWID		X PWID	X PWID	X MSM/TGW, PWID
HCG pregnancy test*	X				

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

¹HIV RNA is highly recommended at baseline, especially in certain situations, and if symptoms of possible acute retroviral syndrome develop while taking PrEP. It is recommended every 3 months as part of PrEP monitoring however, it is not a required test and should not be a barrier to prescribing PrEP.

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

APPENDIX A- ALGORITHM A: PrEP INITIATION 4) LABORATORY- Required Baseline Labs	
<p>Hepatitis B Status</p> <p>-Confirm vaccination or order lab at intake only -Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection. -Do not start PrEP if has current Hepatitis B infection Please see: https://www.cdc.gov/hepatitis/HBV/PDFs/serologicChartv8.pdf for further information</p>	
<p>Step 1: Hepatitis B Vaccine</p> <p><input type="checkbox"/> YES</p>	<ul style="list-style-type: none"> • Confirmation of being fully vaccinated for hepatitis B via ALERT • Attempt to obtain past Hep B surface antibody result to confirm protection after completion of vaccine series or order to check <div style="text-align: right; margin-top: 10px;"></div>
<p><input type="checkbox"/> NO</p> <div style="text-align: center; margin-top: 10px;"></div>	<ul style="list-style-type: none"> • Lack of vaccination is not a contraindication for PrEP • Counsel on risk factors for Hepatitis B and recommend vaccination. OAR 855-019-0280.
<p>Step 2: Hepatitis B surface antigen If no Hep B Vaccination, order Hepatitis B serologies</p> <p><input type="checkbox"/> non-reactive all OR only surface antiGEN and core antiBODY</p>	<p><input type="checkbox"/> reactive or indeterminate surface AntiGEN or core AntiBODY</p> <div style="text-align: right; margin-top: 10px;"></div>
<p>Renal Function Status</p> <p>Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months</p>	
<p><input type="checkbox"/> CrCl > 60 mL/min <input type="checkbox"/> CrCl 30-60 mL/min <input type="checkbox"/> CrCl < 30 mL/min</p>	<p><input type="checkbox"/> CrCl is < 60 ml/min, do NOT use F/TDF</p> <ul style="list-style-type: none"> • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. <p><input type="checkbox"/> CrCl is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- <input type="checkbox"/> CrCl is < 30 ml/min*</p> <ul style="list-style-type: none"> • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease <div style="text-align: right; margin-top: 10px;"></div>
<p>Syphilis/Treponemal Antibody</p> <p>Order lab at initial intake and every 90-180 days depending on risk. ⁵Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS)</p> <p><input type="checkbox"/> non-reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive</p>	<p><input type="checkbox"/> reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above)</p> <div style="text-align: right; margin-top: 10px;"></div>
<p>Gonorrhea, and Chlamydia Screenings</p> <p>Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive Pharyngeal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive Rectal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive</p>	<p><input type="checkbox"/> reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above)</p> <div style="text-align: right; margin-top: 10px;"></div>
<p>Hepatitis C Ab----Optional</p> <p>Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months</p> <p><input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive</p>	<p><input type="checkbox"/> reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP</p> <div style="text-align: right; margin-top: 10px;"></div>
<p>HCG Pregnancy Test—Optional</p> <p>Recommended for: Persons who may become pregnant <u>Frequency:</u> Every 3 to 12 months per patient preference and pharmacist clinical judgment</p>	<p><input type="checkbox"/> Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP</p> <div style="text-align: right; margin-top: 10px;"></div>

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

¹ 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](#).

² County Health Department Directory:

<https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx>

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

APPENDIX B- ALGORITHM B: PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs	
Renal Function Status Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months	
<input type="checkbox"/> CrCl > 60 mL/min <input type="checkbox"/> CrCl 30-60 mL/min <input type="checkbox"/> CrCl < 30 mL/min	<input type="checkbox"/> CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. <input type="checkbox"/> CrCl is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- <input type="checkbox"/> CrCl is < 30 ml/min* • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease
Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. ⁵ Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) <input type="checkbox"/> non-reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above)
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive Pharyngeal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive Rectal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above)
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	<input type="checkbox"/> Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

¹ 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](#).

² County Health Department Directory:
<https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx>

PrEP Prescription

Optional-May be used by pharmacy if desired

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

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

- Truvada® (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**
- Take one tablet by mouth daily for 30 days, #30, 0 refills
 - Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

- Descovy® (emtricitabine/tenofovir alafenamide) 200/25mg tablets**
- Take one tablet by mouth daily for 30 days, #30, 0 refills
 - Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the 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: _____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

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

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

Your patient _____ (name) ____/____/____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on ____/____/____ (Date) for a ____ day supply and follow-up HIV testing is recommended in approximately ____ days ____/____/____ (Date)

This regimen consists of the following (check one):

- | | |
|--|---|
| <input type="checkbox"/> Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
• Take one tablet by mouth daily | <input type="checkbox"/> Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
• Take one tablet by mouth daily |
|--|---|

Your patient has been tested for and/or indicated the following:

<u>Test Name</u>	<u>Date of Test</u>	<u>Result</u>	<u>Needs referral</u>
• HIV ag/ab (4th gen):	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• HIV RNA:	____/____/____	<input type="checkbox"/> detected <input type="checkbox"/> indeterminate <input type="checkbox"/> not detected	<input type="checkbox"/> Yes
• Hepatitis B surface antigen:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Hepatitis C antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Syphilis/Treponemal antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Gonorrhea/Chlamydia:	____/____/____		<input type="checkbox"/> Yes
Urinalysis result:	Pharyngeal test result:	Rectal test result:	
<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	
<input type="checkbox"/> non-reactive	<input type="checkbox"/> non-reactive	<input type="checkbox"/> non-reactive	
• Renal function (CrCl):	____/____/____ mL/min		<input type="checkbox"/> Yes
<input type="checkbox"/> CrCl >60mL/min	<input type="checkbox"/> CrCl 30mL/min - 60mL/min	<input type="checkbox"/> CrCl <30mL/min	
• HCG:	____/____/____	<input type="checkbox"/> positive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Signs/symptoms of acute retroviral syndrome (<input type="checkbox"/> Present <input type="checkbox"/> Not Present) AND potential HIV exposure (<input type="checkbox"/> Yes <input type="checkbox"/> No) in the last 4 weeks and not on PrEP (<input type="checkbox"/> Yes <input type="checkbox"/> No).			<input type="checkbox"/> Yes
• Exposure risk less than 72 hours ago? <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada® is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada® and Descovy® are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional 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: (855) 448-7737. For information about PrEP, please visit the [CDC website](https://www.cdc.gov/hiv).