

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

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 pre-exposure prophylaxis (PrEP) drug regimen.
- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
 - Utilize the standardized PrEP Patient Intake Form (pg.2-3)
 - Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
 - Utilize the standardized PrEP Provider Fax (pg.9)

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

Oregon Board of Pharmacy

Approved: 12/2020

Reviewed:

Modified:

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

(CONFIDENTIAL-Protected Health Information)

Date ____/____/____

Name _____ Date of Birth ____/____/____ Age ____

Please circle your pronouns: He/Him, She/Her, They/Them, Ze/Hir

Healthcare 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: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? ☐ yes ☐ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time ____/____/____ last sex without a condom
3. Do you have oral sex? <ul style="list-style-type: none"> Giving- you perform oral sex on someone else Receiving- someone performs oral sex on you
4. Do you have vaginal sex? <ul style="list-style-type: none"> Receptive- you have a vagina and you use it for vaginal sex Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? <ul style="list-style-type: none"> Receptive- someone uses their penis to perform anal sex on you Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	<input type="checkbox"/> yes <input type="checkbox"/> no
2. Do you see a (healthcare provider) for management of Hepatitis B?	<input type="checkbox"/> yes <input type="checkbox"/> no
3. Have you ever received an immunization for Hepatitis B? If yes, when: <ul style="list-style-type: none"> If no, would you like a Hepatitis B immunization today? <input type="checkbox"/> yes <input type="checkbox"/> no 	<input type="checkbox"/> yes <input type="checkbox"/> no Date of vaccine ____/____/____
4. Do you see a healthcare provider for problems with your kidneys?	<input type="checkbox"/> yes <input type="checkbox"/> no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? <ul style="list-style-type: none"> Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen) 	<input type="checkbox"/> yes <input type="checkbox"/> no
6. Are you currently or planning to become pregnant or breastfeeding?	<input type="checkbox"/> yes <input type="checkbox"/> no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	<input type="checkbox"/> yes <input type="checkbox"/> no

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form
(CONFIDENTIAL-Protected Health Information)

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. Per the CDC, the pharmacist must document a negative HIV test to fill my PrEP prescription. <ul style="list-style-type: none">• I may be able to have tests performed at the pharmacy.• I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.<ul style="list-style-type: none">○ I brought my labs in today <input type="checkbox"/> Yes <input type="checkbox"/> No• I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. <ul style="list-style-type: none">• I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	<input type="checkbox"/> Yes <input type="checkbox"/> No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

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Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Date ____/____/____

Patient Name _____ Date of Birth ____/____/____ Age ____

Preferred pronouns (circle): He/Him, She/Her, They/Them, Ze/Hir

Healthcare Provider's Name: _____

Insurance Provider: _____

Medication allergies: _____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. 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).

Risk Factor:	Notes and considerations
1. Sexual partners	<ul style="list-style-type: none">• MSM activity is highest risk for HIV.• Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time ____/____/____ last sex without a condom	<ul style="list-style-type: none">• Condomless sex greatly increases risk of HIV and STIs.• For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).• Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	<ul style="list-style-type: none">• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals.• STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	<ul style="list-style-type: none">• Receptive vaginal sex can be high risk for HIV.• Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	<ul style="list-style-type: none">• Receptive anal sex has the most risk of HIV of any sex act.• Insertive anal sex has high risk for HIV.• STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	<ul style="list-style-type: none">• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	<ul style="list-style-type: none">• People living with HIV who have undetectable viral loads will not transmit HIV.• For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	<ul style="list-style-type: none">• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	<ul style="list-style-type: none">• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.• Recommend adequate lubrication in persons who use poppers for sex.

One or More Risk Factor Present: ☐ yes ☐ no

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- If no, HIV PrEP is not recommended. Refer to a healthcare provider.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway (CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics below indicate need for referral.*

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
<i>Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing.</i>			
• Syphilis/Treponemal antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
<i>Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.</i>			
• Hepatitis B surface antigen:	____/____/____	<input type="checkbox"/> positive <input type="checkbox"/> negative	<input type="checkbox"/> Yes
<i>Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.</i>			
• Gonorrhea/Chlamydia:	____/____/____		<input type="checkbox"/> Yes
Urinalysis result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	Pharyngeal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	Rectal test result: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	
<i>All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.</i>			
• Renal function (CrCl): SCr _____mg/dL	____/____/____	_____ mL/min <input type="checkbox"/> CrCl >60mL/min <input type="checkbox"/> CrCl 30-60mL/min <input type="checkbox"/> CrCl <30mL/min	<input type="checkbox"/> Yes
<i>CrCl >60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; CrCl <30mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.</i>			
• Signs/symptoms of STI not otherwise specified:	____/____/____	<input type="checkbox"/> Present	<input type="checkbox"/> Yes
• Condomless sex in past two weeks	____/____/____	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes

All required labs are complete: ☐ yes ☐ no

- **If yes, proceed to next section: Medical History.**
- ***If no, obtain required labs before proceeding.***

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

County Health Department Directory:

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

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway (CONFIDENTIAL- Protected Health Information)

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
REFERRAL CONDITIONS	
1. Positive HIV test <i>Needs Referral:</i> <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection <i>Needs Referral:</i> <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Impaired kidney function (<30mL/min) <i>Needs Referral:</i> <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> Truvada is approved for patients with a CrCl >60mL/min. Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
4. Other medications <i>Needs Referral:</i> <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
CONSIDERATIONS	
5. NSAID use Precaution- Counseled on limiting use: <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> 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.
6. Hepatitis B vaccinated If not, would the patient like to be vaccinated? <input type="checkbox"/> yes <input type="checkbox"/> no	<ul style="list-style-type: none"> Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. Counsel on risk factors for Hepatitis B and recommend vaccination. If patient would like to be vaccinated, proceed according to CDC and manufacturer schedule.
7. Pregnant or breastfeeding	<ul style="list-style-type: none"> Pregnancy and breastfeeding are not contraindications for PrEP. Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. Truvada is preferred due to better data in these populations.

One or More Referral Condition(s) Present: ☐ yes ☐ no

- If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.***
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next section: Regimen Selection and Prescribing.***

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway (CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. <ul style="list-style-type: none"> Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference. 	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. <ul style="list-style-type: none"> Only Truvada is FDA approved in these populations. If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management. 	Truvada
NSAID use <ul style="list-style-type: none"> If patient is male or a male to female transgender woman, consider Descovy 	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. <ul style="list-style-type: none"> If patient is male or male to female transgender woman, consider Descovy 	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. <ul style="list-style-type: none"> If patient is male or male to female transgender woman, consider Descovy. 	Descovy
Patient is pregnant or breastfeeding <ul style="list-style-type: none"> Descovy has not been studied in these populations. Truvada is approved in these populations. 	Truvada

*generic versions are acceptable in all cases if available.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway
(CONFIDENTIAL- Protected Health Information)

Prescription:

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

☐ Verified DOB with valid photo ID

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 90 days, #90, 0 refills

-or-

- ☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**
○ 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:	

Dear Provider _____ (name),

Your patient _____ (name) ____/____/____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on ____/____/____ (Date) and follow-up HIV testing is recommended in approximately 90 days ____/____/____ (Date)

This regimen consists of the following:

- | | |
|--|---|
| <input type="checkbox"/> Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets | <input type="checkbox"/> Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets |
| <input type="checkbox"/> Take one tablet by mouth daily for 90 days | <input type="checkbox"/> Take one tablet by mouth daily for 90 days |

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

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Syphilis/Treponemal antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Hepatitis B surface antigen:	____/____/____	<input type="checkbox"/> positive <input type="checkbox"/> negative	<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"/> negative	<input type="checkbox"/> negative	<input type="checkbox"/> negative	
• Renal function (CrCl):	____/____/____ mL/min		<input type="checkbox"/> Yes
<input type="checkbox"/> CrCl >60mL/min	<input type="checkbox"/> CrCl >30mL/min but <60mL/min	<input type="checkbox"/> CrCl <30mL/min	
• Signs/symptoms of STI not otherwise specified:	____/____/____	<input type="checkbox"/> present	<input type="checkbox"/> Yes
• Condomless sex in past two weeks	____/____/____	<input type="checkbox"/> yes	<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:

- 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.

Pharmacy monitoring of HIV PrEP:

- The pharmacy prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment per CDC guidelines.
- 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).