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Utah Guidance For Pre-Exposure and Post-Exposure Prophylaxis of HIV

Approved September 28, 2021

In compliance with Utah Code § 58-17b-627 a Utah licensed pharmacist may prescribe a prescription drug or device within the scope of the pharmacist's training and experience pursuant to Utah Admin. Code § R156-17b-627, the Pre-Exposure Self-Screening Patient Intake Form, the Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway and the Pre-Exposure Provider Fax or the Post-Exposure Self-Screening Patient Intake Form, the Post-Exposure Prophylaxis (PEP) Assessment and Treatment Care Pathway, and the Post-Exposure Provider Fax.

(CONFIDENTIAL- Protected Health Information)

Date _____/_____/_____
Legal Name_____
Sex Assigned at Birth (circle) M / F
Preferred 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: 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? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • 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? • 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)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ 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. The pharmacist must document a negative HIV test to fill my PrEP prescription. • 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. ○ I brought my labs in today □ Yes □ 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.	□ Yes □ 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. • 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.	□ Yes □ 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.	□ Yes □ 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:

Patient Signature: _____ **Date:** _____

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

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

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.

Risk Factor:	Notes and considerations
1. Sexual partners	• 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	• 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	• 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	• 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	• 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	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• 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	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• 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.

1. Is 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:	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
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.			
• Syphilis/Treponemal antibody:	_____/_____/_____	□ *reactive* □ *indeterminate* □ negative	□ *Yes*
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.			
• Hepatitis B surface antigen:	_____/_____/_____	□ *positive* □ negative	□ *Yes*
Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.			
• Gonorrhea/Chlamydia:	_____/_____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ negative	Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative	Rectal test result: □ *reactive* □ *indeterminate* □ negative	
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.			
• Renal function (CrCl): SCr _____mg/dL	_____/_____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.*			
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3. Are all required labs are complete? □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History

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.

→ *See next page for sample language for reactive (inderterminate) STI test.*

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

(CONFIDENTIAL- Protected Health Information)

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.

Utah Department of Health https://ptc.health.utah.gov/local-health-departments/

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 *Needs Referral:* □ *yes* □ no	• 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 *Needs Referral:* □ *yes* □ no	• 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) *Needs Referral:* □ *yes* □ no	• 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 *Needs Referral:* □ *yes* □ no	• 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: □ yes □ no	• 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? □ yes □ no	• 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 Utah Admin Code R156-17b-621
7. Pregnant or breastfeeding	• 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.

4. Are 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 sections: Regimen Selection and Prescription.

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. • 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. • 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 • 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. • 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. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available

PrEP 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:	

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) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily for 90 days
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - 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):	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Syphilis/Treponemal antibody:	_____/_____/_____	☐ *reactive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Hepatitis B surface antigen:	_____/_____/_____	☐ *positive* ☐ negative	☐ *Yes*
• Gonorrhea/Chlamydia:	_____/_____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative	
• Renal function (CrCl): ☐ CrCl >60mL/min	_____/_____/_____ ☐ CrCl 30mL/min - 60mL/min	_____ mL/min ☐ *CrCl <30mL/min*	☐ *Yes*
• Signs/symptoms of STI not otherwise specified:	_____/_____/_____	☐ *present*	☐ *Yes*
• Condomless sex in past two weeks	_____/_____/_____	☐ *yes*	☐ *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.
- 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 specialist and is available every day at: (855) 448-7737. For Information about PrEP, please visit the CDC website.

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

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred 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.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____

Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

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

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

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

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

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

PLUS

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

Notes:

- There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
- Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

***** For any child who is currently in danger of serious injury, or is suspected to be currently in danger of serious injury, please contact Utah Child Protective Services @ 1-855-323-3237.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

PEP Prescription

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

☐ Verified DOB with valid photo ID

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

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil 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: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

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

Pharmacy 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**
- 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.
  - 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 doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the- counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like 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. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 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 antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
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:_____
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:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

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 and Isentress are both 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 at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

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.