Let's PrEP: Law Updates on Pharmacist Prescriptive Authority in HIV Prevention

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Disclosure

- Relevant Financial Conflicts of Interest
 - · CE Presenter: Chloe Ortbals
 - None
 - Mentor: Gary Huynh
 - None
 - Mentor: Karen Gunning
 - None
- Off-Label Uses of Medications
 - None



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Abbreviations

- HIV: human immunodeficiency virus
- AIDS: acquired immunodeficiency syndrome
- ART: antiretroviral therapy
- PrEP: Pre-exposure prophylaxis
- PEP: Post-exposure prophylaxis
- NRTI: nucleoside reverse transcriptase inhibitor
- INSTI: integrase strand transfer inhibitor
- WNL: within normal limit
- F/TDF: Tenofovir Disoproxil Fumarate (TDF) + Emtricitabine (FTC)
- F/TAF: Tenofovir Alafenamide Fumarate (TDF) + Emtricitabine (FTC)



Pharmacist Learning Objectives

- Discuss medical and social concerns HIV PrEP and PEP patients face.
- Apply guideline-directed medication therapy for HIV prevention.
- Review the Utah Pharmacy Practice Act law updates surrounding HIV PrEP and PEP.
- Employ the steps a pharmacist would need to take to prescribe HIV PrEP or PEP for a patient.
- Demonstrate knowledge of resources for medical care for HIV PrEP and PEP.

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Technician Learning Objectives

- Discuss medical and social concerns HIV PrEP and PEP patients face.
- Recognize common medications used in the prevention of HIV.
- Demonstrate knowledge of resources for medical care for HIV PrEP and PEP.

Background

Based on 2019 data, approximately 1.2 million individuals live with HIV in the U.S. with approximately 37,000 new HIV diagnoses.

The most common age group to receive a new HIV diagnosis:

25-29 yo (N= 7,396)

The most common race/ethnicity to receive a new HIV diagnosis:

Black/African American (N= 15,340) The most common transmission category:

Male-to-male sexual contact (N= 24,084)



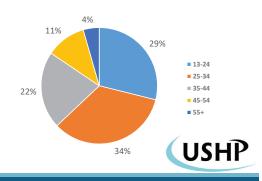
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Utah Background

In 2019, Utah had 135 new cases of HIV

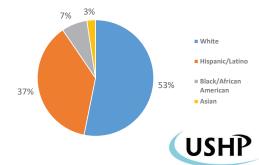
Table 1: HIV Cases per Age Group						
Age Group	Cases	Rate per 100,000				
13-24	39	6.2				
25-34	46	9.7				
35-44	29	6.5				
45-54	15	4.6				
55+	6	0.9				



Utah Background

In 2019, Utah had 135 new cases of HIV

Table 2: HIV Cases per Race/Ethnicity							
Race/Ethnicity	Cases	Rate per 100,000					
White	67	3.3					
Hispanic/Latino	47	9.7					
Black/African American	9	30.5					
Asian	3	4.3					
Others (combined)	9	-					



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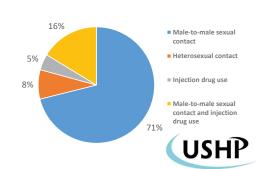
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Utah Background

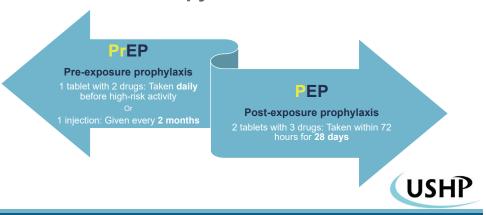
In 2019, Utah had 135 new cases of HIV

Table 3: HIV Cases per Transmission Category

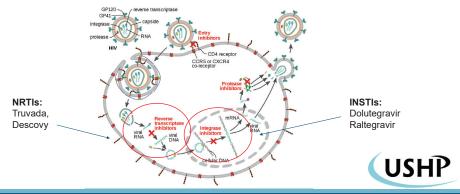
Transmission Category	Cases					
Male-to-male sexual contact	96					
Heterosexual contact	11					
Injection drug use	6					
Male-to-male sexual contact and injection drug use	22					



Medication Therapy in HIV Prevention



HIV Prevention Mechanism of Action



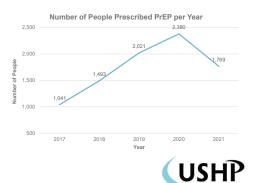
Just how effective is PrEP?

when taken as prescribed

PrEP Coverage in the State of Utah

Table 4: Number of People Prescribed PrEP per Yea

Year	Number of Persons Prescribed
2017	1,041
2018	1,493
2019	2,021
2020	2,380
2021	1,769



Medical & Social Barriers Preventing Access

- Knowledge/awareness of PrEP
- Perception of HIV risk
- Social Stigma
- Provider bias and distrust of healthcare providers/systems
- · Lack of access to medical care
- · Lack of access (or awareness) of financial assistance options
- Side effects/medication interaction concerns



rr, K. H., Agwu, A., & Malebranche, D. (2020). Barriers to the Wider Use of Pre-expi hylaxis in the United States: A Narrative Review. Advances in Therapy, 37(5), 1778

Ending the HIV Epidemic Initiative

75% reduction in new **HIV** infections by 2025

And at least

reduction by 2030



Diagnose all people with HIV as early as possible after infection.



Prevent new HIV transmissions by using proven interventions.



Treat the infection rapidly and effectively to achieve viral suppression.



Respond quickly to potential HIV outbreaks.



Getting to Zero

Getting to Zero is a collaborative initiative that aims to reduce new HIV infections and HIV-related stigma, with the ultimate goal of zero HIV-related deaths in Utah.









RESPOND

Getting to Zero HIV Prevention Strategies

Increase access to PrEP education Increase PEP resources and education statewide Increase representation of impacted communities in the Utah HIV Planning Group Develop two new sexual health initiatives · Increase harm reduction programming for people living with HIV who use drugs Increase funding mechanisms that support PrEP Increase the number of providers prescribing PrEP · Publish a report on PrEP and PEP utilization and usage barriers 2023 · Increase the quality and availability of sexual health data Increase the number of PrEP users in Utah by 50% 2025

Audience Response Question

What are common medical and social barriers HIV PrEP and PEP patients face?

- A. Knowledge/awareness
- B. Social Stigma
- C. Lack of access to medical care or financial assistance
- D. Side effects/medication interactions
- E. All of the above

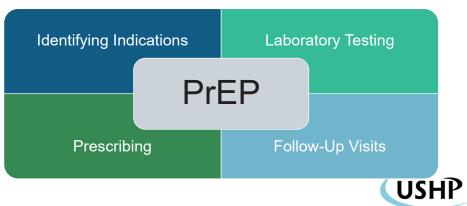


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HIV Prevention Guideline Directed Treatment



Indications for PrEP

Sexually Active Adults and Adolescents

Anal or vaginal sex in the past 6 months AND any of the following:

- · HIV-positive sexual partner
- Bacterial STI in past 6 months
- History of inconsistent or no condom use with sexual partner

Persons Who Inject Drugs

HIV-positive injecting partner

OR

Sharing injection equipment

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Baseline PrEP Laboratory Testing

All of the following conditions must be met:

- Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP
- No signs/symptoms of acute HIV infection
- □ Estimated CrCl ≥ 30 mL/min (for oral medication only)
- No contraindicated medications

Highly Recommended:

- HBV Ag/Ab test
- ☐ STI Testing (syphilis, gonorrhea, chlamydia)
- ☐ Lipid Profile (F/TAF only)



Prescription Medications

Generic	Brand	Dosing	When to Use	Considerations	Precautions	Common Side Effects (≥2%)
Tenofovir Disoproxil Fumarate (TDF) + Emtricitabine (FTC)	Truvada®	1 tablet by mouth daily	Any healthy adult or adolescent at risk for HIV	Available Generic ≤ 90 day supply Weight ≥ 35 kg CrCl ≥60 mL/min Adherence	New onset or worsening renal impairment Decrease in bone mineral density Lactic acidosis or severe hepatomegaly with steatosis	Headache Abdominal Pain Weight loss



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Prescription Medications

Generic	Brand	Dosing	When to Use	Considerations	Precautions	Common Side Effects (≥5%)
Tenofovir Alafenamide Fumarate (TAF) + Emtricitabine (FTC)	Descovy®	1 tablet by mouth daily	Men and transgender women Preferred in persons with osteoporosis or related bone disease	No generic ≤ 90 day supply Weight ≥ 35 kg CrCl ≥30 mL/min Adherence	New onset or worsening renal impairment Lactic acidosis or severe hepatomegaly with steatosis	• Diarrhea

Prescription Medications

Generic	Brand	Dosing	When to Use	Considerations	Precautions	Common Side Effects (≥2%)
Cabotegravir Extended- Release Injectable Suspension	Apretude®	(Optional) 30 mg by mouth daily x 4 week lead-in prior to injection then 600 mg injected into gluteal muscle every 2 months	Persons with difficulty adhering to oral regimens Significant renal disease	Must be given in clinic Weight ≥ 35 kg	Hypersensitivity Hepatotoxicity Depressive Disorders	Injection site reactions Diarrhea Headache Pyrexia Fatigue Nausea Dizziness Abdominal Pain Myalgia Rash Appetite Changes Back Pain Resp. Tract Infection





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Follow-Up

F/TDF and F/TAF	Cabotegravir
Every 3 months:	1 month after first injection:
☐ HIV Ag/Ab test and HIV-1 RNA assay	☐ HIV Ag/Ab test and HIV-1 RNA assay
☐ Medication adherence	,
■ Behavioral risk reduction support	Every 2 months (starting with third injection):
	☐ HIV Ag/Ab test and HIV-1 RNA assay
Every 6 months:	
Assess renal function if age ≥50 or CrCl ≤90 mL/min at PrEP	Every 4 months (starting with third injection):
initiation	 Bacterial STI screening for MSM and transgender women
■ Bacterial STI testing for sexually active patients	
	Every 6 months (starting with fifth injection):
Every 12 months:	□ Bacterial STI screening for heterosexually active patients
 Assess renal function for all patients 	
□ Chlamydia screening for heterosexually active patients	Every 12 months (starting with first injection):
☐ For patients on F/TAF, assess weight, triglyceride, and	☐ Chlamydia screening for heterosexually active patients
cholesterol levels	



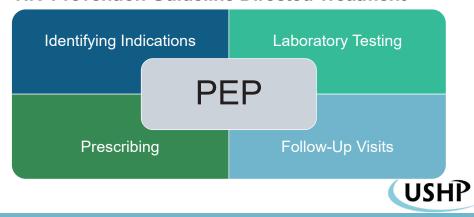
Q: How long does it take for PrEP to be effective?

A: Receptive anal sex = 7 days

Receptive vaginal sex and injection drug use = 21 days



HIV Prevention Guideline Directed Treatment



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Indications for PEP

Nonoccupational Exposure ≤ 72 hours (nPEP)

After sex without a condom

OR

After injection drug use or some other type of nonoccupational bodily fluid exposure

Occupational Exposure ≤ 72 hours (oPEP)

Personnel exposed to body fluids that could be infectious like a needlestick



Baseline PEP Laboratory Testing

- ☐ HIV Ag/Ab testing
- ☐ Hepatitis B serology including:
- ☐ Hep B surface antigen
- ☐ Hep B surface antibody
- Hep B core antibody
- Hepatitis C antibody test
- Serum creatinine
- ☐ ALT/AST
- STI testing
- ☐ Pregnancy test (if applicable)



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Prescription Medications

Generic	Brand	Dosing	Considerations	Precautions	Common Side Effects (≥2%)
Tenofovir Disoproxil Fumarate (TDF) + Emtricitabine (FTC) PLUS Raltegravir OR Dolutegravir	Truvada® + Isentress® Or Tivicay®	Once daily (D) or twice daily (R) x 28 days	Weight ≥ 35 kg CrCl ≥60 mL/min Separation of cations Adherence	New onset or worsening renal impairment Decrease in bone mineral density Lactic acidosis or severe hepatomegaly with steatosis Hypersensitivity reactions	Headache Abdominal Pain Weight Changes Insomnia Dizziness



Follow-Up

F/TDF + Raltegravir or Dolutegravir

2 weeks post-exposure:

- □Complete blood counts
- □Renal and hepatic function tests

6 weeks, 3 months, and 6 months post-exposure:

□HIV Ag/Ab testing



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Patient Case

24-year-old male with 5 male sexual partners; engages in both oral and anal sex; condom use inconsistent

- No chronic medical conditions
- No prior sexually-transmitted infections
- Physical examination unremarkable
- HIV and STI testing one month ago was negative
- Patient preference is to start on an oral regimen



Audience Response Question

Which tests should be sent prior to starting PrEP?

- A. HIV antibody, hepatitis B surface antibody, urinalysis, STI testing, lipid panel
- B. HIV antibody, hepatitis B surface antibody, serum creatinine, STI testing, lipid panel
- C. HIV RNA, hepatitis B surface antibody, urinalysis, STI testing, lipid panel
- D. HIV RNA, hepatitis B surface antibody, serum creatinine, STI testing, lipid panel



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Results of Testing

- HIV negative
- HBV negative
- STI negative
- CrCl 82 mL/min
- Lipid Panel: WNL

Audience Response Question

Which medication should we start?

- A. Tenofovir Disoproxil Fumarate + Emtricitabine (Truvada®)
- B. Tenofovir Alafenamide Fumarate + Emtricitabine (Descovy®)
- C. Cabotegravir Extended-Release Injectable Suspension (Apretude®)
- D. Either A or B
- E. Any of the above



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Timeline of HIV PrEP and PEP Pharmacist **Prescriptive Authority**

California Jan 2020

Colorado Nov 2020

Oregon Jun 2021

Utah Nevada Virginia Missouri New Jersev New York



Utah Timeline

PHARMACY PRACTICE MODIFICATIONS 2021 GENERAL SESSION STATE OF UTAH

Chief Sponsor: Norman K. Thurston Senate Sponsor: Curtis S. Bramble

This bill amends the Pharmacy Practice Act

10 Highlighted Provisions:

7 LONG TITLE

- · amends the definition of the practice of pharmacy to include issuing a prescription 13 for certain prescription drugs and devices;
- 14 • defines the types of prescription drugs and devices that may be prescribed by a
- authorizes the Division of Occupational and Professional Licensing to make rules to
- 17 implement the provisions of this bill.

Pharmacy Practice Act

- ✓ Date Passed: February 25, 2021
- ✓ Date Governor Signed: March 16, 2021
- ✓ Date Effective: May 5th, 2021

Pharmacy Practice Act Rule

- ✓ Open Comment: January 14th, 2022
- ✓ Date Effective: January 27th, 2022

58-17b-627(3)(a) Pharmacy Practice Act

58-17b-627 Prescription of drugs or devices by a pharmacist.

- (1) Beginning January 1, 2022, a pharmacist may prescribe a prescription drug or device if: (a) prescribing the prescription drug or device is within the scope of the pharmacist's training and experience:
- (b) the prescription drug or device is designated by the division by rule under Subsection (3)(a);and
- (c) the prescription drug or device is not a controlled substance that is included in Schedules I, II, or IV of:
- (i) Section 58-37-4; or
- (ii) the federal Controlled Substances Act, Title II, P.L. 91-513.
- (2) Nothing in this section requires a pharmacist to issue a prescription for a prescription drug or device
- (3) The division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:
- (a) designate the prescription drugs or devices that may be prescribed by a pharmacist under this section, beginning with prescription drugs or devices that address a public health concern that is designated by the Department of Health, including:
- (i) post-exposure HIV prophylaxis;
- (ii) pre-exposure HIV prophylaxis;
- (iii) self-administered hormonal contraceptives:
- (iv) smoking cessation; and
- (v) naloxone;



Let's dive deeper...

- A pharmacist can prescribe PrEP and PEP because it addresses a public health concern designated by the Department of Health
- √ A pharmacist must follow guidelines when prescribing a prescription drug (e.g., Statewide Protocol)
- ✓ A pharmacist must refer a patient to an appropriate health care provider or encourage patient to seek further medical care when applicable
- A pharmacist must always follow the laws and regulations

R156-17b-627 Pharmacy Practice Act Rule

Patient Assessment (provided in the statewide protocol)

- · Current health status
- Past medical history
- Allergies
- · Medication sensitivities
- · Rationale for care
- Current medications
- · Determination if referral is needed

Guideline-Directed Treatment

- Centers for Disease Control and Prevention
- Nationally accepted guidelines
- Utah Guidance for Pre-Exposure and Post-Exposure Prophylaxis of HIV



R156-17b-627 Pharmacy Practice Act Rule

Monitoring and Follow Up

- Develop and implement an appropriate follow-up care plan
 - · Monitoring parameters for efficacy and safety
- · Adverse reactions
- Further medical care
- Compliance with requirements in Sections 58-17b-602 & 58-17b-609

Notification of Prescription (provided in the statewide protocol)

- Notify patient's primary care provider or other health care provider within 5 business days of prescribing
- · Must be conveyed by telephone, electronic transmission, or writing
- If no PCP, then prescription notification will be provided to patient



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R156-17b-627 Pharmacy Practice Act Rule

Prescription Requirements

- Must be maintained in patient record for at least 5 years from the date of notification
- · Prescribing pharmacist
- · Pharmacy name
- · Pharmacy phone number
- Patient name
- · Patient date of birth
- · Drug or device
- · Dispense quantity
- · Directions for use
- Refills
- · Identity of the patient's primary care or other health care provider, if any



PrEP Protocol

Indications	Labs	Medication	Follow-Up
Per CDC Guidelines: Anyone who has one or more risk factors for HIV Referral Required: • Existing HIV infection • Existing HBV infection • CrCl ≤ 30 mL/min or under care for chronic kidney disease • Contraindicated home medications	Required: HIV Ag/Ab (within 14 days) Serum Creatinine STI testing (3 sites) Syphilis Gonorrhea Chlamydia HBV surface antigen Screening Required: Signs/symptoms of STI Condomless sex in the past two weeks	Based on pharmacist judgement after patient assessment: Truvada® or generic Descovy® Duration: 30 days with no refills if baseline testing not completed 90 days otherwise Refill quantity only until next scheduled follow-up	Every 3 months: HIV Ag/Ab Every 6 months: STI testing Serum creatinine Annually: For patients on Descovy®, assess weight, triglyceride, and cholesterol levels



nation updated as of February 14th, 2022

PrEP Protocol

Recommended Counseling (at minimum):

- Proper use of medication (dosing, schedule, side effects)
- · Importance of medication adherence
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- · The necessity of follow up care with PCP for usual care
- · Importance and requirement of testing for HIV, renal function, HBV, and STIs

Considerations:

ition updated as of February 14th, 2022

- · Limit NSAID use as it may increase the risk of kidney damage
- · Offer vaccination for Hepatitis B if unvaccinated
- Pregnancy and breastfeeding are not a contraindication to PrEP



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PEP Protocol

Indications	Labs	Medication	Follow-Up
Exposure within 72 hours and no known HIV infection	The pharmacist is required to contact the patient's primary care provider or	Only regimen permitted for pharmacist prescribing at this time:	Pharmacist will contact patient approximately 1 month after initial
Referral Required:	other appropriate provider to		prescription:
 Exposure > 72 hours 	provide written notification	Truvada® PLUS Raltegravir	
 Patients <13 years old 	of PEP prescription and to	AND	6 Weeks:
 Existing HIV infection 	facilitate establishing care	Written individualized care	 HIV Ag/Ab
 Existing HBV infection 	for baseline testing:	plan	 HBV/HCV test
 No established primary 	 HIV Ag/Ab 		• CMP
care provider for follow-	 Serum creatinine 	Duration:	 STI testing
up	AST/ALT	 28-30 days with no refills 	 Pregnancy (if applicable)
 Reduced renal function 	 HBV serology 		
or chronic kidney	 HCV antibody 		3 Months:
disease	STI testing		 HIV Ag/Ab
	 Pregnancy (if applicable) 		 HCV antibody

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nation updated as of February 14th, 2022

PEP Protocol

Recommended Counseling (at minimum):

- · Same as PrEP counseling PLUS:
- Separation of vitamins or supplements with calcium or magnesium by 2 hours
- Importance of taking both medications together to prevent resistance
- Instructions on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- Emergency contraception (if applicable)

Considerations:

- If the case involves sexual assault, patient should also be examined and comanaged by professionals specifically trained for these types of circumstances
- Child protective services must be contacted if a child is potentially a victim of child abuse



A 42-year-old female comes into the pharmacy you work at requesting PEP due to an exposure that happened yesterday after sharing a needle with a stranger who she came to find out is HIV positive.

After a patient assessment you find out:

- PMH: hypertension, GERD, substance abuse (heroin) x1 year with last use yesterday
- · Allergies: NKDA
- Medications: Lisinopril 10 mg daily (last use >1 month ago), Tums 1 tablet daily PRN (last use yesterday)
- Social History: homeless but does have a PCP



formation updated as of February 14th, 2022

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Audience Response Question

What testing would we want in addition to prescribing PEP?

- A. HIV, serum creatinine, STI testing, AST/ALT, HBV/HCV, pregnancy
- B. HIV, serum creatinine, STI testing, HBV/HCV, urinalysis, pregnancy
- C. HIV, serum creatinine, STI testing, lipid panel, pregnancy
- D. HIV, serum creatinine, STI testing, lipid panel, HBC/HCV, urinalysis, pregnancy









Results of Testing

- HIV negative
- HBV/HCV negative
- STI negative
- Pregnancy negative
- CrCl 63 mL/min
- AST 13
- ALT 24





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Audience Response Question

Are we able to prescribe PEP for this patient?

- A. Yes
- B. No, she needs a referral to a PCP



Audience Response Question

What medication regimen would be BEST for this patient?

- A. F/TDF + Raltegravir, twice daily
- B. F/TDF + Dolutegravir, once daily











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Audience Response Question

What medication regimen can we prescribe for this patient?

- A. F/TDF + Raltegravir, twice daily
- B. F/TDF + Dolutegravir, once daily



Audience Response Question

What counseling points needs to be discussed with the patient?

- A. She needs to follow up with the pharmacist or her PCP in 6 weeks for repeat HIV testing.
- B. She needs to separate her PEP from her Tums by at least 2 hours.
- C. Instructions on HIV prevention including not sharing injection equipment.
- D. Importance of medication adherence.
- E. All the above





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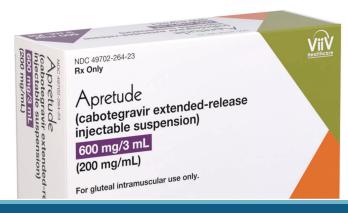
Barriers with Required Labs

Up to the individual pharmacy to establish access to labs

- Salt Lake County Health Department
- Public health services that already provide these types of services Unfortunately, these services may cost the patient additional money Health Department Fees:
- HIV test: free
- STI testing: \$40/test
- HBV: \$45HCV: \$50



What about Cabotegravir?





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ELSEVIER

Contents lists available at ScienceDirect

Journal of the American Pharmacists Association



journal homepage: www.japha.org

RESEARCH NOTES

Patient perspectives of pharmacists prescribing HIV pre-exposure prophylaxis: A survey of patients receiving antiretroviral therapy

- Over 90% of participants stated they would be willing to consult a pharmacist for HIV PrEP information or testing.
- Almost 20% of participants expressed discomfort having a pharmacist prescribe their first HIV PrEP prescription. Reasons include:
 - · Rather consulting their physicians
 - · Reservations about adequate pharmacist training



Resources for Patients

Basic Information about PrEP/PEP

- Salt Lake County Health Department- PrEP
- Utah AIDS Foundation- HIV and STI Info Hotline (English & Spanish)
- CDC PrEP/PEP Page

Online tool for deciding about taking PrEP

• The Stigma Project- Is PrEP Right for Me?

Guides to discussing PrEP with your provider

- Salt Lake County Health Department- PrEP Checklist
- CDC- Talk to your Doctor about PrEP

Tools for finding a PrEP provider near you

- Utah AIDS Foundation PrEP referral form
- PrEPLocator.org

Tools to estimate and pay PrEP costs

- Gilead Sciences- Truvada PrEP Access and Assistance Programs
- Patient Advocate Foundation- Copay Relief
- PrEPCost.org



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Resources for Clinicians

Basic Information

- HIV.gov
- CDC PrEP/PEP Page
- · Project Inform- PrEP Clinical Study Data Sheet

Assessment tool for starting a patient on PrEP

TheBodyPro- Assessment Tool: Is PrEP indicated?

Training Opportunities

- · Utah AIDS Education and Training Center
- · National Association of County and City Health Official PrEP for HIV Prevention Modules

If Cost is an Issue

• "SLC PrEP is Free" through the University of Utah Health

Questions?

HIV Warmline offers consultations for providers from HIV specialists (855)-448-7737

Audience Response Question

You have a patient interested in starting PrEP; however, they have a history of chronic kidney disease and you decide to refer them to a primary care physician. What is one resource to locate a provider for this patient?

- A. CDC
- B. The Stigma Project
- C. PrEPlocator.org
- D. Project Inform



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Summary

Barriers

- Few people are using PrEP even though eligible
- There are many medical and social barriers preventing eligible people from getting on PrEP

Updates

- Licensed Utah pharmacists are now eligible to prescribe PrEP and PEP as of January 2022
- Guideline-directed treatment must be used in addition to the statewide

Resources

There are many resources available for both patients and clinicians in the pursuit of HIV prevention.



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