

PrEP Provider Toolkit



This toolkit is aimed at current or potential PrEP providers. It contains helpful information including PrEP prescribing guidelines, a summary of PrEP efficacy trials, patient eligibility criteria, health insurance coverage/billing, support resources, and a guide to discussing a patient's sexual health

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Additional resources available through the CDC at:

www.cdc.gov/hiv/risk/prep/

www.cdc.gov/actagainstaids/

1. Evidence for PrEP: Key Studies

Men and Transgender Women Who Have Sex with Men Pre-exposure Prophylaxis Initiative (IPrEx) Trial¹

<http://www.nejm.org/doi/full/10.1056/NEJMoa1011205>

- Reduction in risk of HIV acquisition with Truvada® (FTC/TDF):
 - 44% overall
 - 73% in high adherence group²
 - 92% in those with detectable drug levels

Heterosexual Men and Women

Partners PrEP Trial³

<http://www.nejm.org/doi/full/10.1056/NEJMoa1108524>

- Reduction in risk of HIV acquisition with Truvada® (FTC/TDF):
 - 75% overall
 - 90% in those with detectable drug levels

TDF2 Trial⁴

<http://www.nejm.org/doi/full/10.1056/NEJMoa1110711>

- Reduction in risk of HIV acquisition with Truvada® (FTC/TDF):
 - 62% overall

Injection Drug Users

Bangkok Tenofovir Study⁵

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61127-7](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61127-7)

- Reduction in risk of HIV acquisition with Truvada® (FTC/TDF):
 - 49% overall
 - 56% in high adherence group⁶
 - 74% in those with detectable drug levels

¹ Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med.* 2010;363(27):2587-2599.

² Self-reported adherence of >90% during the preceding 30 days.

³ Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med.* 2012;367(5):399-410.

⁴ Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med.* 2012;367(5):423-434.

⁵ Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection among people who inject drugs in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet.* 2013;381(9883):2083-2090.

⁶ Directly observed to be taking ≥71% of days (approximately 5 days/week) and missing no more than two consecutive doses.

2. Is Your Clinic Ready to offer PrEP?

2.1. Clinical Site Checklist

- Clinic is culturally competent to provide care to LGBT population.
- Front-desk staff are aware that PrEP is provided and can triage patient calls and visits appropriately.
- Clinic staff is able to assist with PrEP medication assistance paperwork.
- Healthcare providers are willing to prescribe PrEP and have knowledge of:
 - How to take a detailed sexual history
 - PrEP indications
 - PrEP contraindications/considerations
 - PrEP billing codes
 - Options for paying for PrEP
 - PrEP laboratory monitoring and follow up guidelines
- Laboratory has capacity for:
 - HIV testing every 3 months
 - Monitoring creatinine clearance every 3-6 months
 - STD screening (chlamydia, gonorrhea, and syphilis) every 3 months, focusing on all exposure sites
 - Hepatitis A, B, and C screening
 - Pregnancy testing
 - Urinalysis
- Adherence and risk reduction counseling is available on-site

2.2. Cultural Competency in LGBT Healthcare: Resources

National LGBT Health Education Center⁷

Glossary of LGBT Terms for Healthcare Teams

<https://www.lgbthealtheducation.org/wp-content/uploads/2018/03/Glossary-2018-English-update-1.pdf>

Understanding the Health Needs of LGBT people

<http://www.lgbthealtheducation.org/wp-content/uploads/LGBTHealthDisparitiesMar2016.pdf>

Providing Inclusive Services and Care for LGBT people

<https://www.lgbthealtheducation.org/wp-content/uploads/Providing-Inclusive-Services-and-Care-for-LGBT-People.pdf>

Center of Excellence for Transgender Health⁸

Online Learning: Acknowledging Sex and Gender

http://transhealth.ucsf.edu/video/story_html5.html?lms=1

⁷ National LGBT Health Education Center, A program of the Fenway Institute. Retrieved from: <http://www.lgbthealtheducation.org>. Accessed January 7, 2019.

⁸ The Center of Excellence for Transgender Health, University of California, San Francisco. Retrieved from: <http://transhealth.ucsf.edu>. Accessed January 7, 2019

2.3. Discussing Sexual Health with Your Patients

Included on the following pages is *A Guide for the Healthcare Professionals: Discussing Sexual Health with Your Patients*. Additional resources can be found at <https://nationalcoalitionforsexualhealth.org/tools/for-healthcare-providers> and <https://www.cdc.gov/actagainststids/campaigns/prescribe-hiv-prevention/index.html>.

2.3

A Guide for the Healthcare Professional:
**DISCUSSING
SEXUAL HEALTH**
with Your Patients



Sexual health is an essential element of overall health and well-being, yet medical providers and patients often do not discuss this topic...

Tips for Discussing Sexual Health with Your Patient

Many patients have sexual health questions and want your insight, but are hesitant about initiating the conversation. By asking all your adult and adolescent patients a few essential questions, you help to remove the stigma around discussing sex and normalize these discussions.

Refine your skills at facilitating such talks by practicing the following strategies:

Assess your own comfort by discussing sex with various patient groups and identify any biases that you may have. If you are uncomfortable talking about sex and sexuality, your patient will be too.

Make your patient feel comfortable by establishing a rapport before asking sensitive questions.

Use neutral and inclusive terms such as “partner” and posing your questions in a non-judgmental manner.

Avoid assumptions about your patient based on age, appearance, marital status, or any other factor. Unless you ask, you cannot know a person’s sexual orientation, behaviors, or gender identity.

Try not to react overtly, even if you feel uncomfortable or embarrassed. Pay attention to your body language and posture.

Rephrase your questions or briefly explain why you are asking a question if a patient seems offended or reluctant to answer.

Ensure that you and your patient share an understanding of the terms being used to avoid confusion. If you are not familiar with a term your patient used, ask for an explanation.

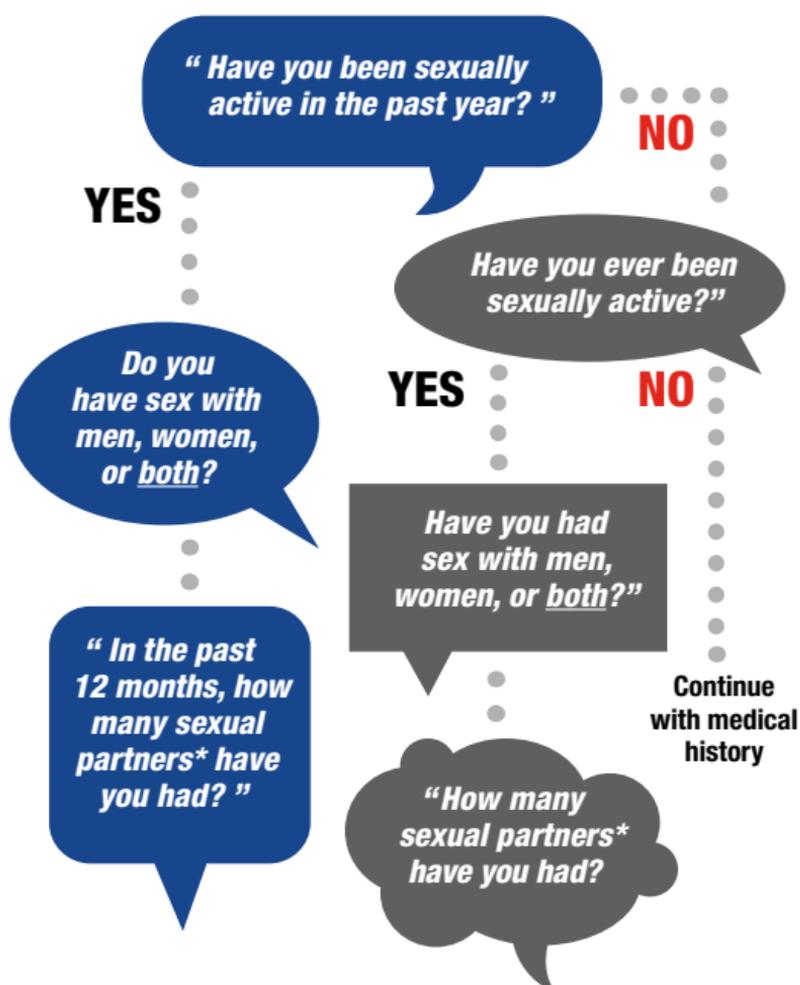
Ask for correct pronouns or terminology when talking to a transgender patient. Use those pronouns and support that patient’s current gender identity, even if their anatomy does not match that identity.

Tips for Asking Sensitive Questions

Transition to asking sensitive questions. Let your patient know that you ask these questions of everyone. If a partner, relative, or caregiver is in the room, ask that person to step into the waiting room. He or she can be invited back after the examination.

“I’m going to ask you a few questions about your sexual health. Since sexual health is very important to overall health, I ask all my patients these questions.

Before I begin, do you have any questions or sexual concerns you’d like to discuss?”



** Ask twice if patient answered “**both**” to the previous question, once for each gender of partner.*

Additional Questions to Ask

This chart contains questions that follow the Centers for Disease Control and Prevention's **5P's** approach to taking a sexual history (Partners, Practices, Past history of STI, Protection, and Pregnancy Prevention/Reproductive Life Plan).

Partners



- Do you know whether your partner has other sexual partners?
- In the past 3 months, have you had sex with someone you didn't know or had just met?
- Have you ever been coerced or pressured to have sex?

Practices



- In the past 3 months, what kinds of sex have you had? Anal? Vaginal? Oral?
(For men who had sex with men: Ask about receptive anal sex, insertive anal sex, or both.)
- Have you or any of your partners used alcohol or drugs when you had sex?
- Have you ever exchanged sex for drugs or money?

Past History of STI



- Have you ever had a sexually transmitted infection (disease)?
If yes: Which STI? Where was the infection? When did you have it? Was (were) your partner(s) treated too?
- Have you ever been tested for HIV?
If yes: How long ago was that test? What was the result?

Protection



- What do you do to protect yourself from STIs, including HIV?
- When do you use this protection? With which partners?
- Have you been vaccinated against HPV? Hepatitis A? Hepatitis B?

Pregnancy Prevention/ Reproductive Life Plan



- Do you have any desire to have (more) children?
 - If yes:** How many children would you like to have?
When would you like to have a child?
What are you and your partner doing to prevent pregnancy until that time?
 - If no:** Are you doing anything to prevent pregnancy?
(Be sure to ask to female-to-male transgender patients who still have female reproductive organs)

Consider asking additional questions to better understand your patient's level of risk, determine whether you need to recommend screenings or vaccinations, and offer appropriate counseling.



To learn more about PrEP & PEP,
access free continuing medical education
opportunities, or receive patient materials, go to:
[**cdc.gov/prescribeHIVprevention**](https://cdc.gov/prescribeHIVprevention)

Adapted from *Sexual Health and
Your Patients: A Provider's Guide*,
published by
The National Coalition for Sexual Health.

For a complete copy of the guide
and other resources, visit:
[**Nationalcoalitionforsexualhealth.org
/tools/for-healthcare-providers**](https://Nationalcoalitionforsexualhealth.org/tools/for-healthcare-providers)



3. Indications for PrEP^{9,10}

Men who have sex with men

- Adult or adolescent male weighing at least 35kg (77lbs) without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see following section)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Heterosexual and men and women

- Adult or adolescent person weighing at least 35kg (77lbs) without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea) diagnosed or reported in the past 6 months

People who inject drugs

- Adult or adolescent person weighing at least 35kg (77lbs) without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in previous sections on this page)

⁹ Centers for Disease Control and Prevention. Pre-exposure Prophylaxis for the Prevention of HIV infection in the United States – 2017 update. A Clinical Practice Guideline. Retrieved from: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Accessed January 8, 2019.

¹⁰ Centers for Disease Control and Prevention. Prescribe PrEP; Pre-exposure Prophylaxis FAQs for the health care professional. Retrieved from: <https://www.cdc.gov/actagainststids/pdf/campaigns/prescribe-hiv-prevention/aaa-php-prep-faq.pdf>. Accessed January 8, 2019.

4. PrEP: Contraindications & Important Considerations

Contraindications

- Documented HIV infection
 - PrEP (TDF/FTC) given to an HIV-infected patient can result in drug resistance^{11,12,13,14}
- Creatinine clearance <60 mL/min¹⁵

Important Considerations

While the following are not absolute contraindications, proceed with caution and consider co-management with or referral to an infectious diseases specialist in patients:

- With Hepatitis B virus (HBV) infection
 - PrEP (TDF/FTC) also treats HBV
 - If PrEP is discontinued, patients with HBV may have rebound viremia¹⁶
- Who are pregnant or are attempting to conceive
 - Need to discuss risks and benefits of PrEP^{17,18}
 - Benefits: decreased risk of acute HIV during pregnancy and decreased risk of mother-child HIV transmission
 - Risks: No data to suggest PrEP (TDF/FTC) increases risk of birth defects, however there is not enough data to exclude the possibility of harm
- With pre-existing risk factors for chronic kidney disease (>65 years of age, hypertension, diabetes, etc.)
 - Discuss possibility of kidney disease
- Taking concomitant nephrotoxic drugs or drugs that interact with PrEP
 - Take thorough medication history and consider discussing with a pharmacist

¹¹ Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquired Immune Defic Syndr*. 2013;64(1):79-86.

¹² Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587-2599.

¹³ Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. 2012;367(5):399-410

¹⁴ Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med*. 2012;367(5):423-434.

¹⁵ Gilead Sciences. Truvada Package Insert. Revised April 2016. Retrieved at: http://gilead.com/~media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf. Accessed April 15, 2019.

¹⁶ Matthews GV, Seaberg EC, Avihingsanon A, et al. Patterns and causes of suboptimal response to tenofovir-based therapy in individuals co-infected with HIV and hepatitis B virus. *Clin Infect Dis*. 2013; 56(9): 87-94.

¹⁷ Siberry GK, Williams PL, Mendez H, et al. Safety of tenofovir use during pregnancy: early growth outcomes in HIV-exposed uninfected infants. *AIDS*. 2012;26(9):1151-1159

¹⁸ Gibb DM, Kizito H, Russell EC, et al. Pregnancy and infant outcomes among HIV-infected women taking long-term ART with and without tenofovir in the DART trial. *PLoS Med*. 2012;9(5):e1001217

- With osteopenia, osteomalacia, or osteoporosis
 - Discuss risk of bone loss with tenofovir (TDF)¹⁹
- Adolescents
 - Younger adolescents at higher risk of renal complications and osteopenia associated with tenofovir (TDF)^{20,21}

Prescribing PrEP for adolescents in Michigan

- The FDA approved Truvada PrEP for adolescents weighing at least 35 kg (77 lbs) in May 2018
- Risks and benefits of PrEP for adolescents should be considered carefully in the context of local laws and regarding health care decision-making by minors. Below is guidance provided by MDHHS legal and summarizes what is permissible:
 - PrEP prescriptions for a minor in the absence of a recent STI and not prescribed in a Title X clinic requires parental consent
 - PrEP prescriptions with or without a recent STI at a Title X clinic does not require parental consent
 - PrEP prescriptions with a recent STI in any type of provider setting does not require parental consent

¹⁹ Liu AY, Vittinghoff E, Sellmeyer DE, et al. Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. *PLoS One*. 2011;6(8):e23688

²⁰ Purswani M, Patel K, Kopp JB, et al. Tenofovir treatment duration predicts proteinuria in a multiethnic United States cohort of children and adolescents with perinatal HIV-1 infection. *Pediatr Infect Dis J*. 2013;32(5):495-500

²¹ Aupibul L, Puthanakit T. Review of tenofovir use in HIV-infected children. *Pediatr Infect Dis J*. 2015;34(4):383-91

5. Paying for PrEP

5.1. Healthcare Provider Resources

Resources for Uninsured Patients:

- Enroll in a healthcare plan <https://www.mibridges.michigan.gov/access/>
 - Medicaid
 - Covers cost of medical visits, labs, and prescription
 - Healthy Michigan Plan
 - Plans have variable co-pays and deductibles, see additional resources for insured patients
- Gilead Truvada for PrEP Medication Assistance Program (Document 5.4)
 - Eligibility: Uninsured and income <500% federal poverty level (FPL)
 - Covers cost of prescription

Resources for Insured Patients:

- Patient Advocate Foundation <https://www.copays.org/diseases/hiv-aids-and-prevention>
 - Eligibility: Insured & income <400% FPL
 - Covers medication co-pays
 - \$7,500/year maximum
- Patient Access Network Foundation
<https://panfoundation.org/index.php/en/patients/assistance-programs/hiv-treatment-and-prevention>
 - Eligibility: Insured & income <500% FPL
 - Covers medication co-pays
 - \$3,600/year maximum
- Gilead Truvada for PrEP Medication Assistance Program (Document 5.4)
 - Eligibility: Insured (no pharmacy benefits) & income <500% FPL
 - Covers cost of prescription
- Gilead Advancing Access Co-pay Coupon Card
<https://www.gileadadvancingaccess.com/copay-coupon-card/enrollment>
 - Eligibility: Insured (excluding federal/state programs), no income restriction
 - Covers medication co-pays
 - \$7,200/year maximum

Note: Programs that are funded by grants may stop/start accepting or renewing applications at points during the funding cycle.

5.2. Billing for PrEP

There are no official billing codes specifically for PrEP (pre-exposure prophylaxis) or PEP (post-exposure prophylaxis). This may change as prescribing for PrEP and PEP becomes more prevalent. Below are a few key reminders about billing for PrEP, PEP and related services. The next page provides ICD-10-CM and CPT codes that can be used now for billing PrEP and PEP related services.

- **All services require a medically necessary (ICD-10) diagnosis code in order to be reimbursed.** Z20.6- contact with and (suspected) exposure to HIV – is classified as an acceptable principal diagnosis/first-listed condition. Always include Z20.6 when coding PrEP or PEP visits. If an insurer requires additional coding clarifying a patient’s risk, Z20.2 (sexual exposure risk) and F11.20 (injection drug use exposure risk) can be added. A medical practice and health department could provide a service that is covered and described by a CPT code and allowable (proper) diagnosis code that justifies reimbursement by the payer.
- **Tests:** HIV, STD, HCV and other tests associated with PrEP and PEP are related to the patient’s ongoing risk of infection, even if the patient is asymptomatic. Screening tests are ordered at initial visit. PrEP initiation visit and following visits use ‘contact with’ codes. Tests which are ordered to evaluate the patient for conditions potentially associated with long-term use of PrEP medication should include the code Z79.899.
- **Remember:** A medical practice or health department can only be paid by an insurance company or government payer for services which are described by a CPT code, performed by a licensed provider (credentialed for the provision of services by the payer) or under the supervision of the credentialed licensed provider, and supported by an allowable ICD-10 diagnosis code.
- **When ordering Hepatitis C tests for patients insured through Medicare:** Medicare covers annual hepatitis C screening only for “high-risk individuals.”
 - A single, once-in-a-lifetime screening test is covered for individuals born from 1945 through 1965 who do not meet the high-risk definition.
 - Per Medicare guidance the initial encounter/test requisition for hepatitis C tests must include diagnosis code Z72.89 (Other problems related to lifestyle).
 - Follow-up encounters/tests for annual hepatitis C testing should include diagnosis codes Z72.89 and/or F11.20 (opioid drug dependence).
 - Consult Medicare guidance documents for specific billing details [here](#).

PrEP & PEP Billing Codes		
PrEP Related Codes – Initial Visit		
Coding for:	ICD-10	Description
Initial Visit	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Initial Tests	Z01.812	Encounter for pre-procedural laboratory examination (Applicable to blood and urine tests prior to treatment or procedure)
	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
	Z11.4	Encounter for screening for human immunodeficiency virus
	Z11.59	Encounter for screening for other viral diseases*
Preventive Medicine CPT Codes	99401	Prevention Counseling approximately 15 minutes
	99402	Prevention Counseling approximately 30 minutes
	99403	Prevention Counseling approximately 45 minutes
	99404	Prevention Counseling approximately 60 minutes
PrEP Related Codes – PrEP Initiation and Follow-Up Visits		
Coding for:	ICD-10	Description
Visit and Tests	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z79.899	Other long term drug therapy (PrEP monitoring)
	Z51.81	Encounter for therapeutic drug level monitoring
	Z20.5	Contact with and (suspected) exposure to viral hepatitis*
	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
Medical Office Visits for PrEP Initiation Evaluation and Management (E/M) Services - CPT Codes	99211-99215	Using E/M codes for established patients: Select the level of service based on the history, exam and medical decision making. If counseling dominates the visit, use time in minutes to select the code. Document the total face-to-face time of the service, the statement that more than 50% of the time was spent in discussion and the nature of the discussion (e.g. I spent 15 minutes in face to face with Mr. XYZ discussing the risks, benefits, limitations, possible complications, dosing, importance of adherence, and required conditions for continued prescribing of PrEP. He voiced and understanding and wishes to proceed).
Opioid abuse- no specific code for IV drug use	F11.20	Opioid dependence, uncomplicated
	F11.21	Opioid dependence in remission
	F11.10	Opioid abuse, uncomplicated
	F11.90	Opioid use, uncomplicated
PEP-related Codes – Initial and Follow-up Visit		
Coding for:	ICD-10	Description
Visit and Tests	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z20.5	Contact with and (suspected) exposure to viral hepatitis
	W46.0XXA	Contact with hypodermic needle (initial)
	W46.1XXA	Contact with contaminated hypodermic needle (initial)
Document is sourced from a number of resources including: NYC Health January 2017, The NASTAD PrEP Manual, and the ICD-10 Manual		

5.3 Getting PrEPED

Included on the following pages is Getting PrEPED, an infographic outlining insurance details for covering the cost of Truvada. A copy of the document can also be found at <https://www.med.unc.edu/ncaidstraining/files/2018/11/Project-Inform-Getting-Prepped.pdf>.

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

You can also use www.prepcost.org to calculate your costs.

YES

(employer, private, insurance marketplace, COBRA, Medicare, Medicaid)

1

Gilead Advancing Access Co-pay Card

gileadcopay.com
877-505-6986

- \$7,200 max/calendar year
- No income limit
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy cannot process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card.

Submit paperwork for reimbursement for all refills. Terms, conditions at gileadcopay.com.

2

Patient Access Network Foundation

panapply.org
866-316-7263

- \$4,800 initial grant, up to \$8,000 max/year, re-apply
- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

3

Patient Advocate Foundation (PAF)

tinyurl.com/PAFhelp,
or copays.org

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help (800-532-5274)

These programs may be subject to funding shortfalls, which may limit enrollment.

FSA (flexible spending account)

Employer FSAs can help cover up to \$2,700 of out-of-pocket costs.

If you're a resident, these state plans may also help if you're insured or uninsured:

- CALIFORNIA: tinyurl.com/CAprepAP
- COLORADO: tinyurl.com/COprepFAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- OHIO: tinyurl.com/OHprepPAPI (cost of services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAprepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

NO

U.S. RESIDENT?

What's the date?

dates may differ in some states

NOV 1 – DEC 15

Enroll in an insurance marketplace

tinyurl.com/stateACAplans

Avoid Bronze plans if you can: they generally have higher costs. Silver plans will offer lower costs for people earning up to 250% FPL (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

You can get insurance at other times for "qualifying life events" such as: pregnancy, loss/change of job, change in household size, change in income, recent move, change in citizenship.

dates may differ in some states

DEC 16 – OCT 31

below 138% FPL / yr
(< \$16,754)

above 138% FPL / yr
(> \$16,754)

below

Enroll in the Gilead MAP.

www.truvada.com/truvada-patient-assistance

What's your income?

60,700

above

Retail cost of Truvada

500% FPL
(2018 FPL: \$12,140 taxable income + \$4,320 per dependent, higher FPL% in Alaska and Hawai'i, 1040 tax form line 7, 1040 EZ line 1)

~ only cost of drug ~
tinyurl.com/FPLincomes

NON-RESIDENT/ UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

5.4. Gilead Advancing Access Application

Included on the following pages is the Gilead Advancing Access Application. A copy of the form can also be found at

https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf.

Complete all applicable sections of the Enrollment Form.

- **Section 1 (required):** Check the box next to each support offering you are requesting from Advancing Access®.
- **Section 2 (required):** Write the name and dosage of the Gilead product you are requesting assistance with from Advancing Access.
- **Section 3 (required):** Complete all fields with the patient's information.
- **Section 4 (required):** Check the appropriate box to indicate if the patient is insured or uninsured.
 - If the patient is insured, fill in the patient's insurance information and fax a copy (front and back) of the patient's insurance card. If the patient has a secondary insurance, check the box to indicate this and fax a copy of the secondary insurance card.
 - If the patient is uninsured, complete Section 9 to apply to the Patient Assistance Program/Medication Assistance Program (PAP/MAP).
- **Section 5 (required):** Complete all fields with the prescriber's information.
- **Section 6:** A healthcare provider must provide the patient's diagnosis and medical information.
- **Section 7 (required):** The prescriber must sign and date this section for reimbursement support and the Patient Assistance Program/Medication Assistance Program (PAP/MAP).
- **Section 8 (required):** The patient (or the patient's representative) must sign and date this section.
- **Section 9 (required only if applying to the Patient Assistance Program/Medication Assistance Program (PAP/MAP)):**
 - Provide the patient's annual household income and household size and complete the additional insurance information portion.
 - The patient must sign and date this section if applying to the PAP/MAP.
 - Attach documentation for all sources of income. If there is no household income, indicate how the patient/household is being supported.

Mail or fax the completed Enrollment Form and all required documentation to the Advancing Access program at the address or fax number below. Both sets of information are necessary to ensure timely enrollment form review. You may complete an electronic enrollment form online at <https://advancingaccessconsent.iassist.com/>.

An Advancing Access case specialist will notify the requestor about the patient's coverage and benefits, alternate funding options and/or qualification for the PAP/MAP, depending on the support requested.

PATIENT CONFIDENTIALITY

Patient confidentiality is of primary importance to us. All patient information will remain confidential. Information may be provided to clinicians, social workers or family members when required to complete the enrollment process and coordinate patient assistance, and to credit bureaus to determine program eligibility with your consent below.

IMPORTANT REMINDER

Please be certain that all applicable pages of the Enrollment Form are completed and include all appropriate documentation when submitting the form. Incomplete forms slow the review process and, in some cases, may require a patient to reapply for the program.

Gilead Sciences, Inc. reserves the right to modify or discontinue the Advancing Access program or terminate assistance at any time. Third-party reimbursement is affected by a range of factors; therefore, Gilead Sciences, Inc. cannot guarantee any coverage or reimbursement.

1. REQUESTED PATIENT SUPPORT (REQUIRED)

CHECK ALL BOXES THAT APPLY

<input type="checkbox"/> Benefits Investigation	<input type="checkbox"/> Prior Authorization and Appeals Information	<input type="checkbox"/> Co-pay Coupon Program Enrollment
<input type="checkbox"/> Patient Assistance Program (PAP) or Medication Assistance Program (MAP) Eligibility Screening		

2. GILEAD MEDICATION PRESCRIBED (REQUIRED)

Product Name:	mg:
If requesting TRUVADA®, please indicate for: <input type="checkbox"/> Treatment <input type="checkbox"/> PrEP/Prevention	

3. PATIENT INFORMATION (REQUIRED)

First Name:	Last Name:	M.I.:	Preferred Language:
Address:	Apt./Unit #	City:	
State:	Zip Code:	Phone #:	SSN# (Last 4 digits):
Email:	DOB:		
Alternate Contact Name:	Phone #:	Relationship:	

CONTACT AUTHORIZATION

I authorize Advancing Access to leave a detailed message, including the name of my prescription, if I am unavailable when they call. Yes No

4. INSURANCE INFORMATION (REQUIRED)

PLEASE INCLUDE A COPY OF THE FRONT AND BACK OF INSURANCE CARD(S)

<input type="checkbox"/> Patient is insured (Please fill out all of the applicable insurance information below. Attach copy—front and back—of patient card.)	<input type="checkbox"/> Patient is uninsured (ie, no health insurance through any public or private payer) SEE OPTIONAL "PATIENT FINANCIAL INFORMATION" SECTION 9 BELOW		
Primary Insurance:	Is this a Medicare Part D plan? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Plan name:	Insurance Phone Number:		
Subscriber Name:	Policy Holder Name:	Policy Holder Relationship to Patient:	
Policy #:	Group #:	Rx Bin #:	Rx PCN #:
<input type="checkbox"/> Check box if patient has secondary insurance coverage and fax a copy of insurance cards, if available.			

5. PRESCRIBER INFORMATION (REQUIRED)

Prescriber Name:	Facility Name:	
Address:	City:	
State:	Zip Code:	Office Contact:
Phone #:	Fax #:	NPI #:
Tax ID #:	State License #:	

6. DIAGNOSIS/MEDICAL INFORMATION

MUST BE COMPLETED BY HEALTHCARE PROVIDER

Diagnosis (Please include ICD code): _____

7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY

By signing this form, I certify that I am prescribing Gilead medication for the patient identified in Section 3. I certify that this prescription medication is medically necessary for the patient and that it will be used as directed. I certify that I will be supervising the patient's treatments and verify that the information provided is complete and accurate to the best of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed to the patient through the Patient Assistance Program/Medication Assistance Program ("PAP/MAP") from any government program or third-party insurer.

If prescribing TRUVADA for PrEP®, I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

I certify that I have received the appropriate written authorization from the patient, in accordance with the Health Insurance Portability and Accountability Act of 1996, applicable state health information privacy law(s), and any other applicable requirements, in order to release the patient's personal and medical information to Gilead and its agents and contractors for the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking prior authorization if needed on the patient's behalf; 3) providing financial assistance, support, and referral support as needed; 4) facilitating the provision of the patient's prescription medication to the patient; 5) contacting the patient with educational materials about the patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program and/or the PAP/MAP; and 6) for Gilead's internal business purposes.

PRESCRIBER SIGNATURE (REQUIRED):	DATE:
----------------------------------	-------

PATIENT NAME: _____ DATE OF BIRTH: _____

8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQUIRED)

I understand that I must complete this enrollment form before I can receive assistance through Gilead Sciences, Inc.'s Advancing Access ("Program") and the Patient Assistance Program/Medication Assistance Program ("PAP/MAP"). As part of this process, Gilead and its agents and contractors (collectively, "Gilead") will need to obtain, review, use and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization.

Information to Be Disclosed: Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV-related status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form.

Persons Authorized to Disclose My Information: My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization.

Persons to Which My Information May Be Disclosed: Gilead, including the third party administrator responsible for the administration of the Program and the PAP/MAP.

Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made to Gilead so that Gilead may use and disclose the PHI for purposes of: 1) completing the enrollment process and verifying my enrollment form; 2) establishing my eligibility for benefits from my health plan or other programs; 3) providing financial assistance, support, and referral support, and communicating with my healthcare providers, including, but not limited to, facilitating the provision of my prescription medication to me; 4) contacting me to evaluate the effectiveness of the Program and/or the PAP/MAP; 5) for Gilead's internal business purposes, including quality control and support enhancing surveys; and 6) to send me marketing information, offers, and educational materials related to my treatment and/or my prescription medication, including the customer relationship marketing program (this use of my personal information is optional and by checking the box under the signatures below, I may opt in).

I understand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure. I understand further that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits or ability to obtain treatment from my healthcare providers will not change, but I will not have access to the support offered by Program and/or the PAP/MAP. I also understand that I may cancel this authorization at any time by notifying Gilead in writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gilead will stop using this authorization to obtain, use or disclose my PHI after the cancellation date, but the cancellation will not affect uses or disclosures of any PHI that have already been made pursuant to this authorization before the cancellation date. I am entitled to a copy of this signed authorization, which expires the earlier of two (2) years from the date it is signed by me or other time period required under the laws of the state in which I reside.

<input type="checkbox"/> By checking this box, I agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my prescription medication, including the customer relationship marketing program.	
SIGNATURE of PATIENT or PATIENT'S REPRESENTATIVE (REQUIRED):	DATE:
Patient Representative's Name (if signing for the patient):	
Patient Representative's Relationship to Patient:	
FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857	

PATIENT NAME: _____ DATE OF BIRTH: _____

9. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPLYING FOR THE PATIENT ASSISTANCE PROGRAM/MEDICATION ASSISTANCE PROGRAM (PAP/MAP)		
Current Annual Household Income: \$		
Number of People in Household supported by above income <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> Other:		
Please submit current documentation for all sources of income (eg, tax return, W2, last 2 pay stubs, etc.). If there is no household income, indicate how the patient/household is being supported:		
ADDITIONAL INSURANCE INFORMATION		
Social Security Number:		
Has the patient applied for ADAP?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, date of application:
Has the patient applied for Medicaid?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, date of application:
Is the patient eligible for Medicaid?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If No, state reason:
Is the patient eligible for VA benefits?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, has the patient tried to obtain the medication through the VA? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, date of application:
Is the patient eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If No, state reason:

APPLICANT DECLARATIONS AND AUTHORIZATIONS (REQUIRED ONLY IF APPLYING FOR THE PAP/MAP)	
<p>I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if Advancing Access becomes aware of any false or inaccurate information or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. If I receive free product through the PAP/MAP, I certify that I will not seek reimbursement or credit for this medication from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this medication or any cost for items associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that the PAP/MAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize the PAP/MAP and its administrator to forward my prescription to a dispensing pharmacy on my behalf. I authorize Gilead and its third party administrator to use the information provided on this form to obtain a personal credit report about me to verify the information on this form and determine my eligibility for the PAP/MAP.</p>	
SIGNATURE OF PATIENT/PATIENT REPRESENTATIVE: (REQUIRED ONLY IF APPLYING FOR PAP/MAP)	DATE:

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

6. Initial PrEP Visit

6.1 Initial Visit Checklist

Assess:

- Indications for PrEP (Document 3)
- Contraindications/considerations for PrEP (Document 4)
- Symptoms of acute HIV infection (Document 6.2)
- Barriers to adherence

Educate:

- CDC PrEP Information Sheet: PrEP for HIV Prevention (Document 6.3)
- CDC Patient Information Sheet - Acute HIV Infection (Document 6.4)
- CDC Truvada Medication Information Sheet for Patients (Document 6.5)
- CDC Taking Daily Medication (Document 6.6)
- Risk reduction counseling (condom use, safe injection practices, etc.)

Laboratory studies:

- HIV test (rapid HIV Ab test, 4th generation Ab/Ag test [preferred], or HIV RNA PCR)
- Creatinine clearance
- Hepatitis B screening (surface antigen, surface antibody, core antibody)
- Hepatitis C screening (antibody)
- Urine pregnancy test for women
- Urethral, rectal, and pharyngeal (based on reported sexual practices) gonorrhea and chlamydia screening
*See [CDC Clinical Practice Guideline](#) for STI screening guidance
- Syphilis screening

Prescription, vaccinations, and follow up:

- After confirmed negative HIV test, give 30 day prescription for FTC/TDF (Truvada®) 1 tablet daily
- Give hepatitis A, hepatitis B, and HPV vaccinations as appropriate
- Schedule follow up appointment just prior to end of 30 day prescription

6.2. PrEP Clinical Visits: Screening for Acute HIV

Signs & Symptoms of Acute HIV Infection

Flu-like or mono-like syndrome with:

- Fever
- Fatigue
- Night sweats
- Arthralgia and myalgia
- Diffuse maculopapular rash
- Generalized lymphadenopathy
- Headache
- Pharyngitis
- Diarrhea

Signs and symptoms of acute HIV infection typically occur a few days after HIV acquisition and can last for days to months.

What to do if there is concern for acute HIV infection

- Send blood for HIV viral load*
- Defer PrEP until confirmed HIV negative

*See [CDC Clinical Practice Guideline](#) for HIV testing/confirmation algorithm.

If the patient is HIV positive

- Counsel patient on HIV status
- Assure prompt linkage to HIV care provider
- Report to local health department

6.3. CDC PrEP Information Sheet: PrEP for HIV Prevention

Included on the following pages is the *PrEP Information Sheet: PrEP for HIV Prevention* from the CDC. A copy can also be found at

https://www.cdc.gov/hiv/pdf/prep_gl_patient_factsheet_prep_english.pdf .

PrEP Information Sheet

Pre-exposure Prophylaxis (PrEP) for HIV Prevention

Frequently Asked Questions

What is PrEP?

“PrEP” stands for preexposure prophylaxis. The word “prophylaxis” (pronounced pro fil ak sis) means to prevent or control the spread of an infection or disease. The goal of PrEP is to prevent HIV infection from taking hold if you are exposed to the virus. This is done by taking a pill that contains 2 HIV medications every day. These are the same medicines used to stop the virus from growing in people who are already infected.

Why take PrEP?

The HIV epidemic in the United States is growing. About 50,000 people get infected with HIV each year. More of these infections are happening in some groups of people and some areas of the country than in others.

Is PrEP a vaccine?

No. PrEP medication does not work the same way as a vaccine. When you take a vaccine, it trains the body’s immune system to fight off infection for years. You will need to take a pill every day by mouth for PrEP medications to protect you from infection. PrEP does not work after you stop taking it. The medication that was shown to be safe and to help block HIV infection is called “Truvada” (pronounced tru va duh). Truvada is a combination of 2 drugs (tenofovir and emtricitabine). These medicines work by blocking important pathways that the HIV virus uses to set up an infection. If you take Truvada as PrEP daily, the presence of the medication in your bloodstream can often stop the HIV virus from establishing itself and spreading in your body. If you do not take the Truvada pills every day, there may not be enough medicine in your blood stream to block the virus.

Should I consider taking PrEP?

PrEP is not for everyone. Doctors prescribe PrEP for some patients who have a very high risk of coming in contact with HIV by not using a condom when they have sex with a person who has HIV infection. You should consider PrEP if you are a man or woman who sometimes has sex without using a condom, especially if you have a sex partner who you know has HIV infection. You should also consider PrEP if you don’t know whether your partner has HIV infection but you know that your partner is at risk (for example, your partner inject drugs or is having sex with other people in addition to you) or if you have recently been told by a health care provider that you had a sexually transmitted infection. If your partner has HIV infection, PrEP may be an option to help protect you from getting HIV infection while you try to get pregnant, during pregnancy, or while breastfeeding.

How well does PrEP work?

PrEP was tested in several large studies with men who have sex with men, men who have sex with women, and women who have sex with men. All people in these studies (1) were tested at the beginning of the trial to be sure that they did not have HIV infection, (2) agreed to take an oral PrEP tablet daily, (3) received intensive counseling on safer-sex behavior, (4) were tested regularly for sexually transmitted infections, and (5) were given a regular supply of condoms.

Several studies showed that PrEP reduced the risk of getting HIV infection.

- Men who have sex with men who were given PrEP medication to take, were 44% less likely to get HIV infection than were those men who took a pill without any PrEP medicine in it (a placebo). Forty-four percent was an average that included men who didn't take the medicine every day and those who did. Among the men who said they took most of their daily doses, PrEP reduced the risk of HIV infection by 73% or more, up to 92% for some.
- Among men and women in couples in which one partner had HIV infection and the other partner initially did not ("HIV-discordant" couples), those who received PrEP medication were 75% less likely to become infected than those who took a pill without any medicine in it (a placebo). Among those who said they took most of their daily doses, PrEP reduced the risk of HIV infection by up to 90%.
- In one study of men and women who entered the study as individuals (not as a couple), PrEP worked for both men and women in one study: those who received the medication were 62% less likely to get HIV infection; those who said they took most of their daily doses, were 85% less likely to get HIV infection. But in another study, only about 1 in 4 women (<26%) had PrEP medication found in their blood when it was checked. This indicated that few women were actually taking their medication and that study found no protection against HIV infection.

More information on the details of these studies can be found at www.cdc.gov/hiv/prep.

Is PrEP safe?

The clinical trials also provided safety information on PrEP. Some people in the trials had early side effects such as an upset stomach or loss of appetite but these were mild and usually went away within the first month. Some people also had a mild headache. No serious side effects were observed. You should tell your doctor if these or other symptoms become severe or do not go away.

How can I start PrEP?

If you think you may be at high risk for HIV, talk to your doctor about PrEP. If you and your doctor agree that PrEP might reduce your risk of getting HIV infection, you will need to come in for a general health physical, blood tests for HIV, and tests for other infections that you can get from sex partners. Your blood will also be tested to see if your kidneys and liver are functioning well. If these tests show that PrEP medicines are likely to be safe for you to take and that you might benefit from PrEP, your doctor may give you a prescription after discussing it with you.

Taking PrEP medicines will require you to follow-up regularly with your doctor. You will receive counseling on sexual behaviors and blood tests for HIV infection and to see if your body is reacting well to Truvada. You should take your medicine every day as prescribed, and your doctor will advise you about ways to help you take it regularly so that it stands the best chance to help you avoid HIV infection. Tell your doctor if you are having trouble remembering to take your medicine or if you want to stop PrEP.

If I take PrEP can I stop using condoms when I have sex?

You should not stop using condoms because you are taking PrEP. If PrEP is taken daily, it offers a lot of protection against HIV infection, but not 100%. Condoms also offer a lot of protection against HIV infection if they are used correctly every time you have sex, but not 100%. PrEP medications don't give you any protection from other infections you can get during sex, but condoms do. So you will get the most protection from HIV and other sexual infections if you consistently take PrEP medication and consistently use condoms during sex.

How long do I need to take PrEP?

You should discuss this with your doctor. There are several reasons that people stop taking PrEP. If your risk of getting HIV infections becomes low because of changes that occur in your life, you may want to stop taking PrEP. If you find you don't want to take a pill every day or often forget to take your pills, other ways of protecting yourself from HIV infection may work better for you. If you have side effects from the medication that are interfering with your life or if blood tests show that your body is reacting to PrEP in unsafe ways, your doctor may stop prescribing PrEP for you.

6.4. CDC Information about Acute HIV Infection and PrEP

Included on the following pages is the *Patient Information – Acute HIV Infection and PrEP* from the CDC. A copy can also be found at https://www.cdc.gov/hiv/pdf/prep_gl_patient_factsheet_acute_hiv_infection_english.pdf.

Patient Information Sheet – *Acute HIV Infection*

Information about Acute HIV Infection and PrEP

What is acute HIV Infection?

HIV stands for human immunodeficiency virus. This is the virus that causes AIDS.

Acute HIV infection is a name for the earliest stage of HIV infection, when you first get infected with the HIV virus. It is sometimes also called primary HIV infection. Many people with acute HIV infection have the following:

- A fever
- A tired feeling
- Swollen lymph nodes (also called lymph glands)
- Swollen tonsils (also called tonsillitis)
- A sore throat
- Joint and muscle aches
- Diarrhea
- A rash

These signs and symptoms of acute HIV infection can begin a few days after you are exposed to HIV and usually last for about 14 days. They could last for just a few days, or they could last for several months.

You might not realize your illness is acute HIV infection. For one thing, you may not have known that the person you had sex with had HIV infection. And the signs and symptoms of HIV infection may feel just like other common virus infections like flu, a cold, sore throat, or mononucleosis (mono).

What tests can show that I have acute HIV infection?

When HIV enters your body, it moves inside white blood cells called CD4 lymphocytes. HIV takes over the CD4 cells and makes billions of copies of the virus each day. The virus spread through your body.

Your body tries to defend itself against HIV by making antibodies (these antibodies try to block the virus from spreading in your body). Most HIV tests check to see if antibodies against HIV are in your blood. But it takes a few weeks before your body makes enough antibodies for the usual HIV tests to see them.

However, when you have acute HIV infection, you have a high amount of the HIV virus in your blood. Special tests can measure the amount of HIV in your blood. At the time you have acute HIV infection, you probably won't have enough HIV antibodies in your blood to measure, but you will have enough virus to measure. So if the blood tests do not find any antibody but do see the virus, your doctor will know that you're feeling sick because you have acute HIV infection.

How does it help to find out I have HIV at an early stage?

First, PrEP is used to help lower your chances of getting HIV infection. If you already have acute HIV infection you should not take PrEP.

Second, while PrEP helps protect people, especially when they take their doses every day, it is still possible to get HIV infection. So if you are taking PrEP and have the signs and symptoms mentioned above, it is important to see your doctor to be checked. If you have some other infection, like the flu, you should continue your PrEP medicines but if it is discovered that you have acute HIV infection, you should stop taking PrEP as soon as your tests show that you have HIV infection.

Third, people who take PrEP for more than a couple of weeks while they have HIV infection can easily develop virus that can't be treated with those same drugs (resistant virus). So finding out quickly that you have HIV infection and stopping PrEP can protect your long term health and keep your treatment options open.

And fourth, when people have lots of virus in their body during acute HIV infection, they are more likely to pass the virus on to people they have sex with, especially since they may not know yet that they have gotten infected. For example, if your last HIV test result was negative and your partner also had a recent negative HIV test result, you might choose to have sex without a condom just at the time when it's very likely you would pass the virus on. So the sooner you know you have become infected, the more careful you can be to protect others from getting HIV infection.

How is HIV treated?

People who have HIV infection are treated with combinations of 3 or more medicines that fight HIV. Some doctors start people on treatment medications as soon as they become infected; other doctors wait for a while because the greatest benefits to a person's health are seen after they have been infected a while. Early treatment also reduces the chances that a person with HIV infection will pass the virus on to their sex partners.

What do I do if I suspect I might have acute HIV infection?

First, contact your doctor's office and arrange to be examined and have the right blood tests.

Second, discuss with your doctor whether to stop your PrEP medications or continue them until your test results are back.

Third, be especially careful to use condoms and take other safer sex measures to protect your partner(s).

6.5. CDC Truvada Medication Information Sheet for Patients

Included on the following pages is the *Truvada Medication Information Sheet for Patients* from the CDC. A copy can also be found at

https://www.cdc.gov/hiv/pdf/prep_gl_patient_factsheet_truvada_english.pdf

Truvada Medication Information Sheet

Truvada Medication Information Sheet for Patients

Brand name: Truvada (tru va duh)

Generic name: tenofovir disoproxil fumarate and emtricitabine

Why is this medication prescribed?

- Truvada is one of several medications that are currently used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.
- Truvada is now being used to *prevent* HIV infection.
- Truvada is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection
- When you take Truvada to prevent HIV infection, doctors refer to this use as “pre-exposure prophylaxis” or “PrEP”.

How does Truvada (PrEP) help prevent HIV infection?

- HIV is a virus that attacks your body’s immune cells (the cells that work to fight infections).
- The 2 medications that make up Truvada (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.
- If you take Truvada as PrEP daily, the presence of the medication in your bloodstream can sometimes stop the virus from establishing itself and slow the spread of HIV in your body.
- By itself, PrEP with Truvada does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

How should this medicine be used?

- You must take one tablet of Truvada by mouth every day .
- Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada without talking to your doctor. When your supply of Truvada starts to run low, contact your doctor or pharmacist to get more.
- You may be at higher risk of becoming infected with HIV if you miss doses or stop taking Truvada than if you take it every day.

What special precautions should I follow?

Before taking Truvada (tenofovir and emtricitabine) you must do the following:

- Tell your doctor and pharmacist if you are allergic to tenofovir, emtricitabine, or any other medications.
- Tell your doctor and pharmacist about all prescription and nonprescription medications, (vitamins, nutritional supplements, and herbal products) you are taking. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor if you have or have ever had kidney or liver disease.
- Tell your doctor if you become pregnant or if you are breastfeeding

What special dietary instructions should I follow?

- Continue your normal diet unless your doctor tells you otherwise.

What should I do if I forget a dose?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

You may experience the following side effects while taking Truvada:

- upset stomach
- headache
- vomiting
- loss of appetite

These side effects usually fade during the first month of taking Truvada for PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

Truvada may cause other side effects. Some side effects can be serious. Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- fever or chills especially with
- sore throat, cough, rash or other signs of infection

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (at <http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

How should I store Truvada in my home?

- You should keep Truvada in the container it came in, tightly closed, and out of reach of children.
- You must store it at room temperature and away from excessive heat and moisture.
- Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

What should I do in case of emergency/overdose?

- In case of overdose, call your local poison control center at 1-800-222-1222. If the person has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

- Do not let anyone else take your medication.
- Ask your pharmacist if you have any questions about refilling your prescription.
- Write a list of all of your prescription and over-the-counter medicines, as well as any vitamins, minerals, or other dietary supplements that you take.
- Bring your medication list with you each time you visit a doctor or if you are admitted to a hospital. Keep it with you always in case of emergencies.

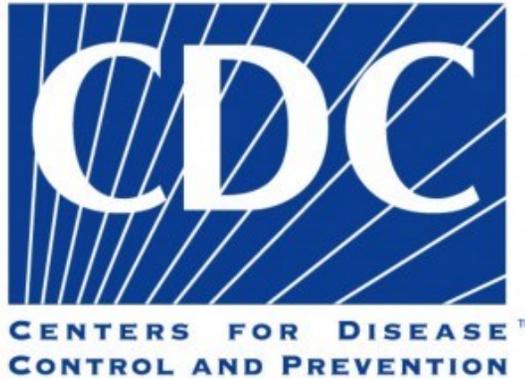
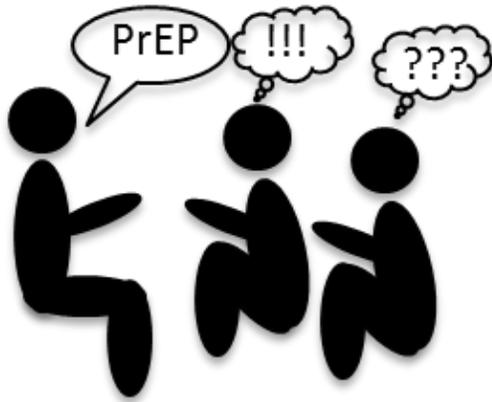
6.6. CDC Taking Daily Medication

Included on the following pages is the *Taking Daily Medication* pamphlet from the CDC. A copy can also be found at

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-adherence.pdf>.

Still Unsure?

If you have a concern or don't understand something, speak up. Ask your health care provider.



**Division of HIV/AIDS Prevention,
National Center for HIV/AIDS,
Viral Hepatitis, STD and
TB Prevention**

Centers for Disease Control
and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027 USA

Phone: 800-232-4636

Are you taking PrEP medication to stay HIV negative?

**A Pill A Day
Keeps HIV
Away**

**Taking
Daily
Medication**



Take Charge of Your Health

Taking your PrEP medicine is critical to keep from getting HIV. For PrEP to work, you need to have enough medicine in your body. When you miss doses, you make it harder for the medicine to protect you.

MON	TUES	WED	THURS	FRI	SAT	SUN
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X

Taking PrEP every day gives you the most protection.

Not taking PrEP every day greatly lowers your protection against HIV.

MON	TUES	WED	THURS	FRI	SAT	SUN
X	X				X	
			X	X		
X			X		X	
				X		X
	X	X				

Is PrEP All You Need?

PrEP is one important tool for protecting yourself from HIV. No method offers 100% protection. While taking your PrEP medicine, you should also reduce your exposure to HIV by using:

- Condoms during sex
- Clean injection equipment if you inject drugs

Together, these methods offer more protection.

Is Taking a Pill Daily Tough? You Can Do It

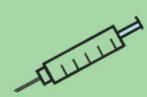
- Do you forget to take your pills?
 - ⊗ Add an app to your phone that reminds you when it's time to take your pill
 - ⊗ Make it a part of your daily routine
 - * Take the pills at the same time each day
 - * Take your pill at the same time as another daily activity like brushing your teeth
 - ⊗ Plan to take pills with you when you won't be at home or are traveling
- Are you worried about possible side effects?
 - ⊗ Side effects are not common, if they happen:
 - * They are mild and do not last long
 - * Ask your doctor how to manage them
- Do you want help in taking your medicine?
 - ⊗ Talk to another PrEP user about what works for them
 - ⊗ Find a PrEP user support group or online forum
 - ⊗ Ask friends to remind & support you
 - ⊗ Find a community program that can assist you
 - ⊗ Use other services
 - * Pharmacists
 - * Social workers
- Are you worried about paying for your medicine?
 - ⊗ Ask your doctor to explain drug assistance programs that might help with payment
- Are problems with alcohol or other substances getting in the way?
 - ⊗ Talk to your doctor about treatment
 - ⊗ Use support groups and programs to stay on track
 - ⊗ Seek counseling to support your mental health

Medicines for Prevention

PrEP is the newest of many uses of medicine to prevent unwanted health outcomes



Birth control pills to prevent pregnancy



Flu shots before winter season each year



Using an inhaler before exercising to prevent asthma



PrEP to prevent HIV

Resources

My PrEP Experience Blog
<http://myprepexperience.blogspot.com>

CDC PrEP Patient Brochures
http://www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr.pdf

7. PrEP Follow-Up Visits

7.1. PrEP 30-day Visit Checklist

Assess

- Side effects
- Symptoms of acute HIV infection
- Adherence and barriers to adherence

Educate

- Reiterate adherence techniques
- Continued risk reduction counseling

Laboratory studies

- No routine labs, obtain as clinically indicated

Prescription, vaccinations, and follow up

- Give 60 day (or 30 days with 1 refill) prescription for FTC/TDF (Truvada®)
- Give hepatitis A, hepatitis B, and HPV vaccinations as appropriate
- Schedule follow-up appointment just prior to end of 60 day prescription

7.2. PrEP Side Effects and Nephrotoxicity

Common Side Effects:

- Nausea/vomiting Diarrhea
- Decreased appetite Headache
- Side effects typically resolve within the first month of taking FTC/TDF (Truvada®).

Nephrotoxicity:

- If creatinine clearance falls below 60mL/min, discontinue PrEP
- If creatinine clearance declines significantly but remains above 60mL/min:
 - Obtain urinalysis. If new proteinuria and/or glycosuria, evaluate for Fanconi syndrome with serum and urine phosphate levels. If Fanconi's present, discontinue PrEP.
 - If no evidence of Fanconi's syndrome, repeat creatinine clearance in 2-4 weeks. If stable and remains >60ml/min can continue PrEP. If kidney function continues to worsen, discontinue PrEP.
 - Most creatinine elevations resolve with medication discontinuation.²²

²² Solomon MM, Lama JR, Glidden DV, et al. Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. AIDS.2014;28(6):851-859.

7.3. Routine PrEP Follow-up (every 3 months)

Assess

- Side effects (Document 7.2)
- Symptoms of acute HIV infection (Document 6.2)
- Adherence and barriers to adherence
- Ongoing indication for PrEP

Educate

- Reiterate adherence techniques
- Continued risk reduction counseling

Laboratory studies (every 3 months)

- HIV test (rapid HIV Ab test, 4th generation Ab/Ag test, or HIV RNA PCR)
- Urine pregnancy test for women
- Urethral, rectal, and pharyngeal screening for gonorrhea and chlamydia
*See [CDC Clinical Practice Guideline](#) for STI screening guidance
- Syphilis screening
- Creatinine clearance for patients with risk of kidney disease

Laboratory studies (every 6 months)

- Creatinine clearance for patients without risk of kidney disease (should be checked at initial visit, 3 month visit, and then every 6 months)
- Urinalysis for patients with risk of kidney disease

Prescription, vaccinations, and follow up

- After confirmed negative HIV test, give 90 day prescription for FTC/TDF (Truvada[®]) 1 tablet daily
- Give hepatitis A, hepatitis B, and HPV vaccinations as appropriate
- Schedule follow up appointments for every 3 months

8. Local Resources

8.1. Michigan HIV Consultation Program

Henry Ford Health System 24-hour Telephone

- Urgent questions: (313)-575-0332
- Non-urgent questions: Submit to www.henryford.org/hivconsult
- For non-urgent questions, responses are given within 24-48 hours
- The Michigan Department of Health and Human Services (MDHHS) and the Henry Ford Health System (HFHS) are pleased to announce the Michigan HIV Consultation Program to address questions from the health care providers about HIV-related issues.
- The Michigan HIV Consultation Program is set up to answer questions from Michigan health care professionals regarding:
 - HIV Disease Management
 - HIV Drug Interaction
 - HIV Occupational and Non-Occupational Post-Exposure Prophylaxis (PEP/nPEP)
 - HIV Pre-exposure Prophylaxis (PrEP)
 - Perinatal HIV treatment

8.2. Michigan PrEP Payment Guide

Included on the following pages is the *Michigan PrEP Payment Guide*. A copy of the guide can also be found at

https://www.michigan.gov/documents/mdhhs/Michigan_PrEP_Payment_Guide_532011_7.pdf.

Michigan PrEP Payment Guide



1/1/2019

Pre-Exposure Prophylaxis (PrEP) Prescription Payment Options

Pre-exposure Prophylaxis (PrEP) is a once-daily pill which reduces the risk of HIV acquisition when used in with other HIV prevention strategies. PrEP is recommended as a prevention option for individuals at substantial risk of acquiring HIV infection. This guide contains information about payment assistance programs to decrease financial barriers to PrEP.

Michigan PrEP Payment Guide

Pre-exposure Prophylaxis (PrEP) Prescription Payment Options

INTRODUCTION

PrEP (Pre-Exposure Prophylaxis) is a once daily medication to help prevent HIV infection in people who are

HIV-negative but at substantial risk of HIV infection. PrEP was approved by the FDA in 2012. The U.S. Centers for Disease Control and Prevention (CDC) issued clinical practice guidelines in 2014, and [updated guidance in 2017](#).

Most insurance plans cover PrEP medication and associated provider visits/screening tests, but the amount of coverage can vary by individual plan. Insurance companies can change their drug formularies at any time, so it's important to verify medication coverage directly with a plan before enrolling. This guide contains information about payment assistance programs to decrease financial barriers to PrEP and is organized based on what type of insurance coverage you have, if any.

If you are looking for information on local prescribers of PrEP and other HIV prevention services, please visit the State of Michigan - Division of HIV and STD Programs website at www.michigan.gov/hivstd.

To assess your HIV infection risk, the CDC has a great tool online that lets you access information that is individually tailored to your needs. Visit the website www.cdc.gov/hivrisk/.

For additional information and local community engagement, visit [PrEP Facts on Facebook: facebook.com/groups/PrEPFacts/](#).

FOR PATIENTS WITHOUT INSURANCE

- Need help enrolling in a healthcare plan?
 - [PrEPCost.org](https://www.prepcost.org) is an online tool that helps clients and navigators evaluate cost and coverage for PrEP, covering on-and-off marketplace health plans.
 - If you are part of the LGBT community, [Out2Enroll](https://www.out2enroll.org) provides strategies to help enrollment efforts. You can also find information on Transgender Health, same-sex couples, and other helpful information when it comes to insurance and enrollment.
 - Help with open enrollment can be found at [healthcare.gov](https://www.healthcare.gov).
 - [Federal Poverty Level](https://www.federalpovertylevel.com)
- Michigan Medicaid
 - Michigan Medicaid covers the cost of medical visits, lab fees, and prescription costs for PrEP.
 - To apply, please visit the [MI Bridges](https://www.mibridges.org) website, or call the application help line at 1-855-276-4627
- Healthy Michigan Plan
 - These plans all have different co-pays and deductibles.
 - Apply online at www.michigan.gov/mibridges, by calling 1-855-789-5610, or visit your [local department of Human Services office](#).
- [Gilead's Truvada for PrEP Medication Assistance Program](#)
 - The Gilead Medication Assistance Program provides assistance to HIV-negative adults within the United States who need financial assistance or do not have insurance get access to Truvada for PrEP.
 - This program is for the uninsured and underinsured.
 - Applicants cannot make more than 500% of the national poverty level (\$60,700 for person or household number of 1). Additional guidelines [here](#).
 - Applicant needs to have proof of residency
 - This can include a driver's license, state I.D., or utility bill in applicant's name.
 - Proof of income is required
 - If no proof of income, Gilead needs to know how you are supported.
 - Prescription form from prescribing physician is also needed.
 - A program application must be submitted online or faxed. You can access the application [here](#).

For more information or to find out if you are eligible for this assistance program, please call 1-855-330-5479, Monday – Friday between the hours of 9:00a.m. and 8:00p.m. (Eastern)

FOR PATIENTS WITH INSURANCE

- Sign-up for the Gilead Co-Pay Coupon Card
 - The card can be applied to medication co-pays.
 - The maximum amount that this card covers is \$7,200/year, with no monthly limit.
 - Requirements:
 - You must be a resident of the U.S., Puerto Rico, or U.S. Territories.
 - You must be 18 years or older to use the card for yourself or a minor.
 - The card is limited to only one person and it is not transferable.
 - The card is NOT available to you if you are currently enrolled in any state or federally-funded assistance program, such as Medicaid or Medicare Part D.
 - You also do not qualify if you reside in the Medicare Part D prescription coverage gap.
 - For more information, visit www.gileadadvancingaccess.com/copay-coupon-card or call 1- 877-505-6986

- Patient Access Network Foundation
 - The Patient Access Network (PAN) Foundation provides help to people whose access to medication is limited. Once an application is submitted and approved, PAN will help pay for a portion of your PrEP prescription.
 - \$3,600 maximum amount per year. Can be applied to medication co-pays
 - Requirements:
 - Patient needs to have primary insurance that will pay for at least some PrEP medication
 - Patient needs to be HIV-negative and at high-risk of acquiring HIV
 - Must live in and receive treatment in the United States
 - Your income must fall below 500% of the Federal Poverty Level.
 - For more information, please call 1-866-316-7263

- Patient Advocate Foundation
 - \$7,500 maximum amount per year. Can be applied to medication co-pays
 - There are 4 ways to apply for this program
 - Your treating physician's office can assist you with making the application for assistance by using the provider portal 24/hours a day at www.copays.org/providers.
 - Your pharmacy that is dispensing your prescribed medications can assist you with making the application for assistance via the pharmacy portal 24/hours a day at www.copays.org/pharmacy.
 - You or someone you designate to assist you can apply at [www/copays.org/patients](http://www.copays.org/patients).
 - Applications can also be submitted via phone by calling 866-512-3861, and option 1, to be connected directly to a specialist for Co-Pay Relief.
 - Requirements:
 - Patient needs to be insured and the insurance must cover the medication (PrEP) cost
 - Must have a current prescription of PrEP
 - Patient must live and receive treatment within the United States
 - Income level for an applicant must fall below 400% of the Federal Poverty Level.

INFORMATION FOR YOUR PRIMARY CARE PHYSICIAN

- If your PCP (Primary Care Physician) needs more information or has questions about PrEP, please have them call the Michigan HIV Consultation Program at (313)-575-0332, run by the Henry Ford Health System. This telephone service is for physicians only and is available 24- hours a day. This hotline allows Michigan health care providers to receive a prompt response to HIV prevention and care questions from experts at the Henry Ford Health System Infectious Disease Division.
- Gilead has created a webpage that provides information regarding Truvada for PrEP for 3 specific audiences: [Healthcare Providers](#), [HIV-negative persons](#) who might use or be interested in PrEP, and [educators](#) who work within the local community and with its members.
- [NASTAD](#) (National Alliance of State and Territorial AIDS Directors) has created a billing code guide to help physicians navigate everything PrEP.

Additional Resources

- Lambda Legal
 - If you are trying to get on PrEP and your health care provider refuses to prescribe it or your insurance won't cover it, feel free to contact Lambda Legal's Help Desk at 1-866-542-8336 or visit lamdalegal.org/help. Lambda Legal was founded in 1973 and is the oldest and largest national legal organization. Lambda's mission is to achieve full recognition of the civil rights of lesbians, gay men, bisexuals, transgender people and those with HIV through impact litigation, education and public policy work.
- Project Inform – projectinform.org/prep
 - Project Inform is a nonprofit organization that fights the HIV and hepatitis C epidemics by helping assure the development of proper and effective treatments and a cure; helping individuals make better informed decisions about their health; advocating for affordable and accessible healthcare; and promoting medical strategies that prevent new infections from occurring. This link provides access to free educational booklets and PrEP educational videos, along with many other services.
 - Centers for Disease Control and Prevention Act Against AIDS Campaign: www.cdc.gov/actagainstaids/
- [My PrEP Experience](#)
 - This website that is managed by the AIDS Foundation of Chicago and shares real stories about individuals who have chosen to use PrEP as a form of HIV prevention. If you have used PrEP or would like to share your experience, you can send videos, audio links, or text to myprepexperience@gmail.com.
- U.S. Department of Veterans Affairs
 - Access and payment assistance may also be available through the [Department of Veterans Affairs](#). The number to call is 1-877-222-8387