University of Arizona's PrEP Pilot Program

PACIFIC AIDS EDUCATION & TRAINING CENTER

THE UNIVERSITY OF ARIZONA
College of Medicine

THE UNIVERSITY OF ARIZONA
INFECTIOUS DISEASES

What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention strategy where people without HIV take anti-HIV medications daily to reduce their risk of becoming infected if they are exposed to the virus. When someone is exposed to the virus through sex or injection drug use, these medicines work to keep the virus from establishing infection.

Considerations

- Today, more than 1.1 million people are living with HIV in the United State.
- CDC estimates +/- 50,000 people in the United States are newly infected with HIV each year
- Nearly two thirds of new infections in MSM
- PEP limitations
- PrEP is a newer concept that has been widely identified as a method to prevent HIV

Consider this case…

Dan is a 30 yr old MSM who estimates he uses condoms about 80 – 85% of the time. He has had 3 partners in the last 6 month and has never used injection drugs.. Is he a good candidate for PrEP?

1. Yes, definitely
2. Probably but I'm not sure
3. No, he is not a good PrEP candidate
4. No idea

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CDC PrEP Guidelines
Who should take PrEP?

	MSM	Heterosexual Women and Men	Injection Drug Users
Potential indicators of substantial risk of acquiring HIV infection	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work ▪ In high-prevalence area or network	▪ HIV-positive injecting partner ▪ Sharing injection equipment ▪ Recent drug treatment (but currently injecting)

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CDC. PrEP Guideline. 2014

PrEP at Petersen Clinic

Goal: To provide individuals at high risk for HIV infection with consultation and referral services concerning Pre-Exposure Prophylaxis (PrEP) in accordance to CDC PrEP Treatment Guidelines.

Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: • HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment • At 3 months and every 6 months thereafter, assess renal function • Every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

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PrEP Program Development

Assessment Components:

1. Risk Factor Assessment

   Screens patient to see if he/she meets eligibility criteria to receive PrEP consultation.

2. Knowledge and Readiness Survey

   Reviews patient's knowledge about PrEP and measures readiness to start treatment.

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PrEP Community Assessment: Risk Factor Assessment (DRAFT)

HIV prevention survey

A. Demographic data

1. What is your age?
   18-29 30-39 40-49 ≥50

2. What is your gender?
   Male
   Female
   Transgender (male to female)
   Transgender (female to male)

3. Are you of Hispanic, Latino/a or Spanish origin?
   Yes
   No
   Prefer not answer

4. What is your racial background? (Select all that apply)
   White
   Black or African American
   Asian
   American Indian or Alaskan Native
   Native Hawaiian or Other Pacific Islander
   Other
   Prefer not answer

B. Social data

1. Have you used any injection drugs in the past 6 months?
   Yes
   No
   If yes, what?

C. Sexual history

1. Have you been sexually active with men, women or both in the past 6 months?
   Yes
   - Men
   - Women
   - Both

   No (Stop here)

2. Have you had any unprotected sex (vaginal or anal) in the past 6 months?
   Yes
   No
   I don't know

3. Have you had unprotected sex (vaginal or anal) in the past six months with someone who uses injection drugs?
   Yes
   No
   I don't know

4. Have you had sex (vaginal or anal) in the past six months with a person who is HIV-positive?
   Yes
   No
   I don't know

5. Have you been diagnosed with a sexually transmitted infection (STI) in the past 6 months?
   Yes
   No
   I don't know

   If yes, which of the following did you have?
   - Syphilis
   - Gonorrhea
   - Chlamydia
   - Genital herpes
   - Genital warts
   - Unsure
   - Other

6. If you are a woman or transgender, have you had unprotected sex in the past 6 months with a man who also had sex with men?
   Yes
   No
   I don't know

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PrEP Community Assessment: Knowledge and Readiness Survey

Knowledge and readiness survey:

1. How much do you estimate your risk for getting HIV?
   1 2 3 4 5 6 7
   Not at all at risk — Extremely at risk

2. Do you know there is a medication (PrEP) that you can take to prevent you from getting HIV?
   Yes — No (Skip to question…7)

3. Where did you hear about it? (Check all that apply)
   Close friend
   Doctor or other medical worker
   Event
   Facebook/twitter
   Family member
   Google search
   Newspaper/magazine article
   Partner
   Television or radio
   Other (please specify)

4. What do you think your risk for getting HIV will be if you take the medication (PrEP)?
   1 2 3 4 5 6 7
   Extremely lower — Will not change — Extremely higher

5. Do you think the medication (PrEP) willhave side effects?
   1 2 3 4 5 6 7
   Extremely unlikely — Extremely likely

6. Are you aware that this medication can be prescribed to you by physicians within our community?
   a. Yes No

7. The Petersen Clinic at U of A is offering consultations to see if you would be a good candidate for this medication to decrease your risk for getting HIV. Are you interested in being referred to them for further evaluation?
   i. 1 2 3 4 5 6 7
   b. Not at all interested — Extremely interested

8. If you are not interested in the medication (PrEP), please explain: (Choose all that apply)
   a. I don't believe it works
   b. I don't want to take more pills
   c. I think it will make me get side effects
   d. I think it will make me get HIV
   e. I am not at a high risk for getting HIV
   f. I am concerned about the cost
   g. I don't want to see a doctor
   h. I don't want to discuss my risk with others
   i. Other alternatives are available (eg condoms..)
   j. Other (please specify)

Pending Inclusions: risk category, insurance status, HIV testing frequency, and previous PCP visit frequency

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UofA's PrEP Clinical Protocol (draft)

First Step: Complete Risk/Eligibility Assessment

Risk assessments and clinical eligibility for UA's PrEP program

- If patient does NOT meet eligibility for PrEP consult, referral to community organization for ongoing prevention discussions (SAAF, PCHD, or COPE)
- If patient MEETS eligibility for PrEP, referral to UA PrEP Coordinator. PrEP Coordinator assists with visit preparation.

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UofA's PrEP Clinical Protocol (draft)

Second Step: Preparation for Treatment

1. Initial laboratory screenings
2. Consultation with Infectious Disease (ID) physician, PrEP recommendation provided to patients as clinically indicated, thorough discussion of treatment plan and implications for non-compliance, and initial treatment course initiated **(90 day prescription)**
3. PrEP patients referred to primary care/ID Resident Clinic for ongoing monitoring and treatment. 90 day refills with completion of required screenings

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UofA's PrEP Clinical Protocol (draft)

Laboratory Screening (pre-visit and ongoing)

Patient completes blood draw at laboratory using 4th generation HIV testing technology

Initial Screenings	Frequency if on PrEP
HIV 1/2 antibody/antigen	One month after initiation of PrEP (retention), q 3 months
Hep B Ag/Ab	q 12 months, unless vaccinated
HCV Ab	q 12 months
Hep B core antibody	Initial only
RPR	q 3 months
GC/CD Urine	q 3 months
BUN/c	q 6 months
Pregnancy (women)	q 3 months

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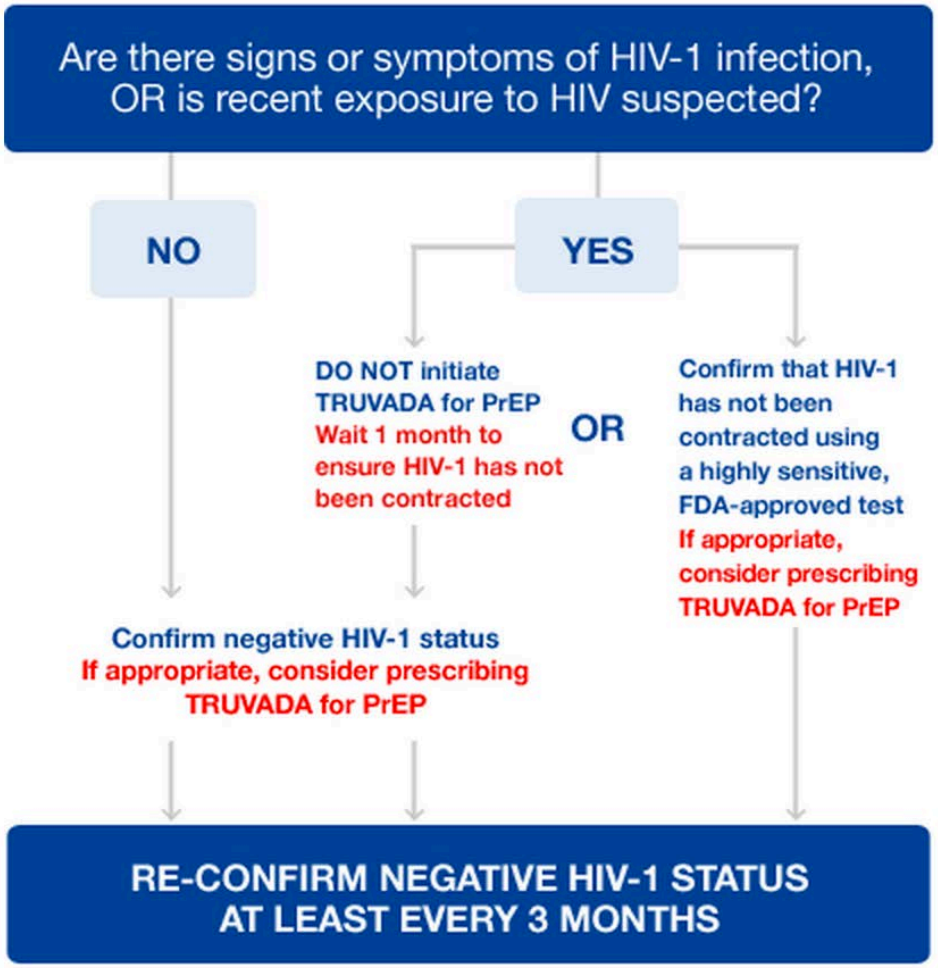
Testing and Retesting to Confirm Negative HIV Status



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https://start.truvada.com/hcp/confirm-negative-hiv1-status

Reducing HIV Risk Behaviors

- Create a trusting clinical environment
- Have **ongoing dialogue** about risk reduction and treatment adherence
- Reinforce that **PrEP is not always effective** but that, with other prevention methods (consistent condom use, discontinuing drug injection or never sharing injection equipment) confers very high levels of protection

Program Snapshot

Most common reasons for using PrEP:

MSM

HIV partner

Inconsistent condom use

HIV partner and trying to get pregnant

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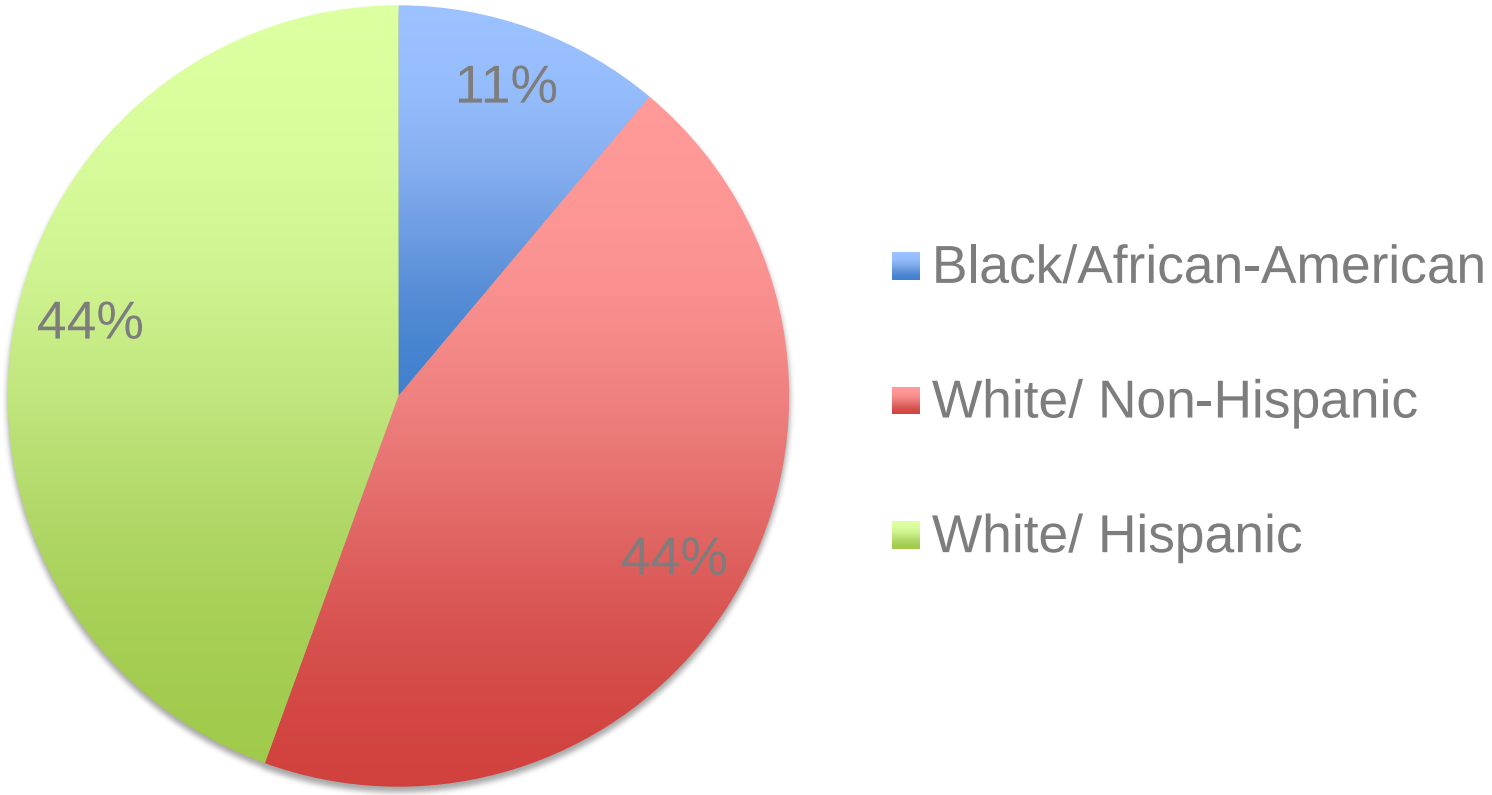
Program Snapshot

Race/ Ethnicity of Petersen PrEP Patients



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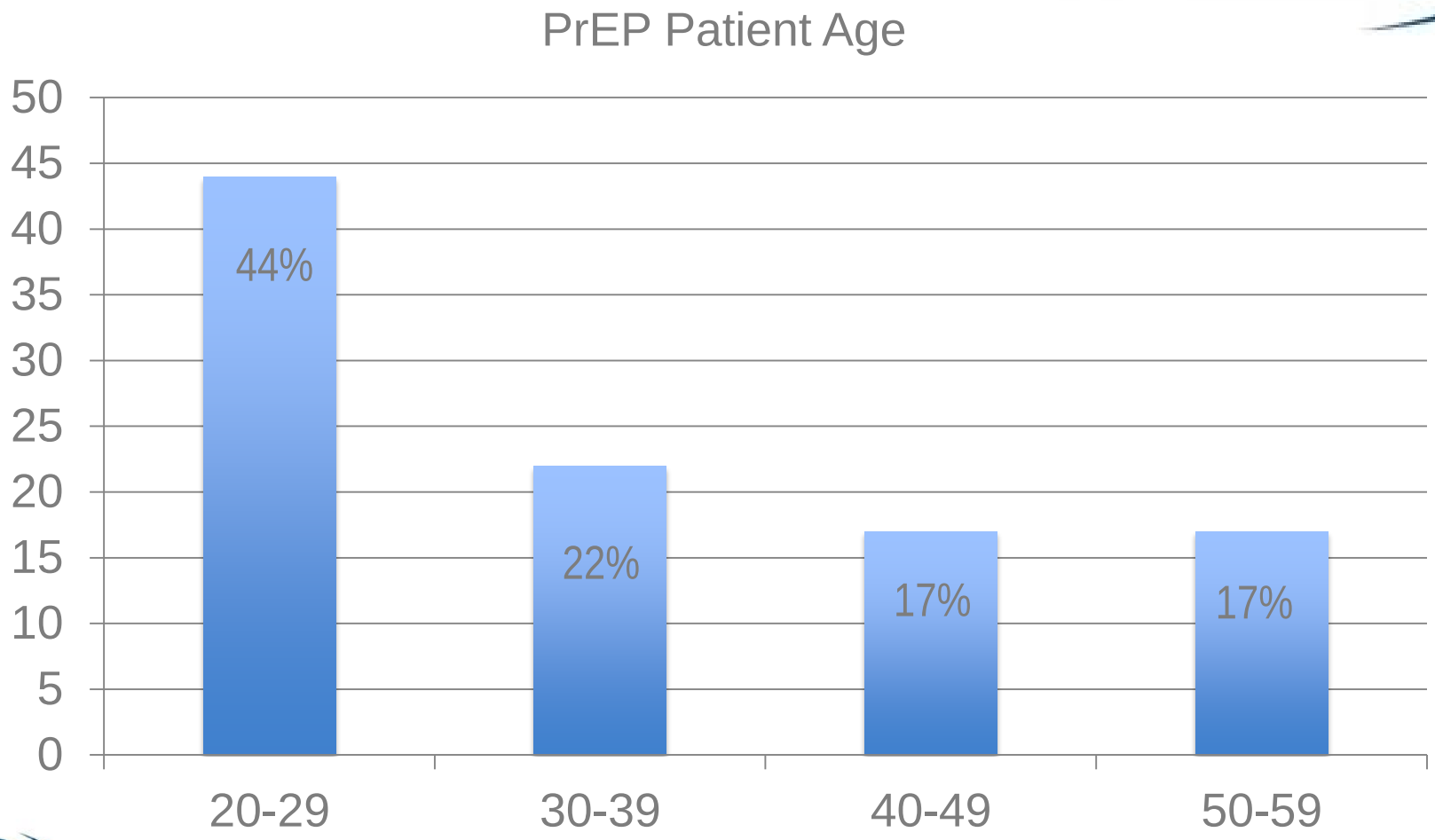
Program Snapshot



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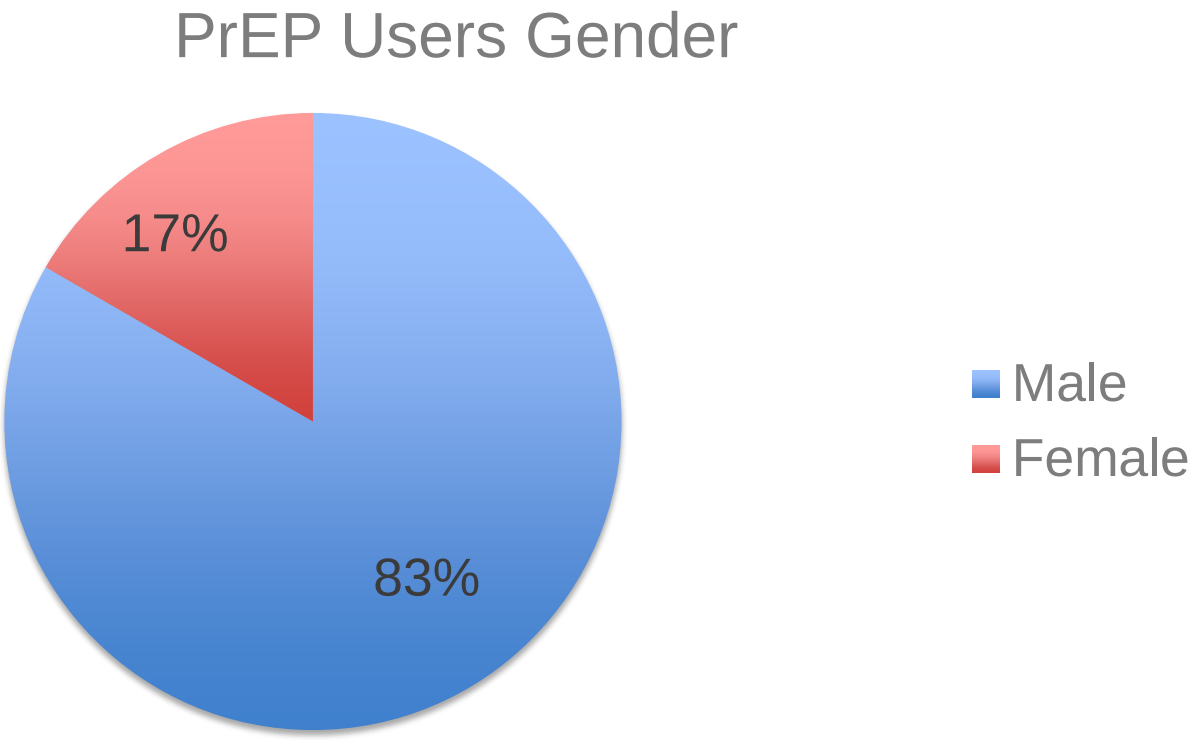
Program Snapshot



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PrEP Access to Medication

PrEP for insured:

- Covered by all commercial insurance companies and Medicaid.
- Most insurance plans require Prior Authorization
- Must provide HIV negative test result

GILEAD's Co-Pay Card Program

- Assists patients with Commercial Insurance by providing $300/month towards co-pay.

Patient Access Network Foundation

- Assists patients with Commercial Insurance and Medicare
- $4,000/year towards co-pay*.
- < 500% FPL

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ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

PROJECT INFORM

www.projectinform.org/prep

YES

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

What are your costs?

$300

below

First, sign up for the Gilead Co-pay Card

gileadcopay.com
877-505-6986

- Up to $300/mo maximum/year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- 12-month enrollment
- Residents of US, Puerto Rico
- Not used with state or federally funded plans, such as Medicare (apply to PAN Foundation).

If the pharmacy doesn't accept Gilead's Co-pay Card, keep sales and pharmacy receipts. Call the number on the back of co-pay card. Submit paperwork for reimbursement for every refill.

and/or

When possible, use the Gilead Co-pay Card first, and then your PAN Foundation account.

above

Also, sign up at the PAN Foundation

panfoundation.org/hiv-treatment-and-prevention
866-316-7263

- $4,000/year, may re-apply
- Income below 500% FPL
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- Residents of US
- Pharmacies can bill PAN Foundation directly

FSA (flexible spending account)
If employer offers an FSA, it can help cover up to $2,550 of out-of-pocket costs.

On Medicaid?
Medicaid should cover medical costs related to PrEP. If you encounter barriers to coverage, consult a legal advocate.

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31

Enroll in an insurance marketplace

obamacarefacts.com/state-health-insurance-exchange/

Avoid Bronze plans if you can: they generally have higher costs. Silver plans will offer lower costs for people earning up to 250% FPL ($29,425). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment
You can get insurance during the rest of the year for "qualifying life events" such as: pregnancy, loss or change of job, change in household size, change in income, recent move, change in citizenship.

FEB 1 – OCT 31

below 138% FPL / yr (< $16,242) → Check if you're eligible for your state Medicaid plan.

above 138% FPL / yr (> $16,242)

NON-RESIDENT/ UNDOCUMENTED?

To get care, find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get an insurance plan through marketplace/employer.

IF NO

What's your income?

$58,850

below

Enroll in the Gilead MAP.

www.truvada.com/truvada-patient-assistance

500% FPL
(2015 FPL: $11,770 taxable income, 1040 tax form line 7, 1040 EZ line 1)

~ only drug costs ~

above

Retail cost of Truvada

If you're a resident, these state plans may also help:
Washington State PrEP DAP: http://tinyurl.com/WAprepDAP (cost of drug)
New York PrEP-AP: http://tinyurl.com/NYprepAP (cost of services)

UPDATED AS OF JULY 9, 2015

PrEP Access to Medication

PrEP Patient Assistance Program for Uninsured:

GILEAD

- Assists HIV Negative adults in the U.S. who do not have insurance. www.truvada.com

**UA does not currently have resources to provide clinical care (labs and outpatient services) to PrEP patients. Exploring mutual care possibilities for uninsured patients.*

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PrEP Resources for Patients

- **UA Petersen Clinics:** hiv.medicine.arizona.edu
- **Arizona AETC:** arizonaaetc.arizona.edu
- **CDC Basic PrEP Q&As:** www.cdc.gov/hiv/basics/prep.html
- **Truvada Website:** www.truvada.com (info on PrEP as well as the medication assistance program for uninsured individuals)
- **PrEP Facts:** prepfacts.org
- WhatisPrEP.org

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