

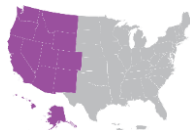
Nevada 2022

Virtual PrEP Institute

April 5-6, 2022

PrEP Navigation Essentials

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POPULATION HEALTH DIVISION
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
CENTER FOR LEARNING & INNOVATION

PrEP Navigation Essentials

No financial disclosures.

PrEP navigation is...

accessing PrEP for sexually active adults and adolescents, as well as those planning to be sexually active, **with as few barriers as possible.**

PrEP Navigation Essentials

PrEP navigation is also...

- providing sex-positive care and empowering people to take an active interest in their sexual health.
- supporting people in their efforts to navigate healthcare and social service systems.
- providing culturally and linguistically appropriate services and referrals and **addressing stigma**.
- educating and partnering with community organizations and providers.
- **providing PEP education.**

PrEP Navigation Essentials

Talking Points about PrEP

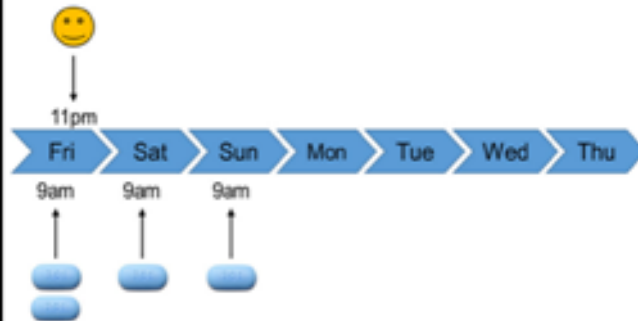
- Studies show PrEP reduces risk of getting HIV from sex by up to 99% when used as prescribed.
- 1 pill/day, every day. Skipping doses reduces effectiveness.
- Possible side effects: upset stomach, nausea, loss of appetite, vomiting, fatigue, and dizziness. Most side effects are mild and usually go away within the first month. Many people do not experience side effects.
- Follow-up includes testing for HIV and STIs every 3 months, testing kidney function every 3-12 months.
- PrEP does not protect against STIs or pregnancy; condoms can still be used to prevent pregnancy and transmission of most STIs.

Talking Points about PrEP

- 2-1-1 PrEP or event-driven PrEP for anal sex (TDF/FTC only)

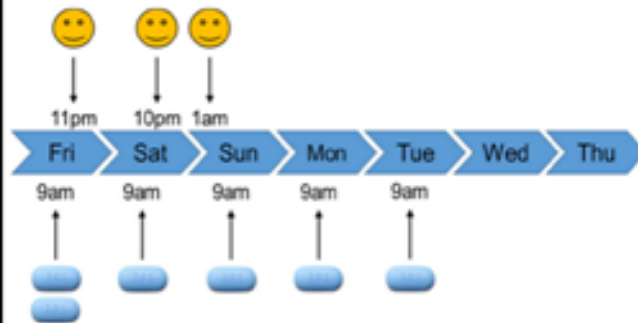
Example 1: One sex episode.

2 PrEP tablets 2-24 hours before sex; 1 PrEP tablet 24 hours after and another 48 hours after the double dose.



Example 2: Multiple sex episodes.

Continue 1 PrEP tablet every 24 hours until 2 days after last "sex day."



- Injectable long-acting PrEP: more later

PrEP Navigation Essentials

Scenario #1: Tad (he/him/his)

- 29yo, identifies as Black, trans man, bisexual. Employed, stably housed, insured.
- Sexually active with 3 different regular partners: 2 cisgender females and 1 cisgender male. Sometimes engages in group sex with cis- and transgender people (mix of known and unknown).
- Came to clinic today because DIS called him to say he was a contact to syphilis. Has heard of PrEP but thought it was just for gay men.

Question #1: How would you proceed with Tad (check all that apply)?

- ☐ Treat for syphilis and provide education
- ☐ Wait until syphilis test comes back to decide on treatment
- ☐ Evaluate for PEP
- ☐ Provide PrEP education
- ☐ Based on Tad's interest in PrEP, prescribe TAF/FTC (Descovy)
- ☐ Based on Tad's interest in PrEP, prescribe TDF/FTC (Truvada or generic).

What are the basic steps in PrEP navigation?

- ① Identify/engage/educate patient
- ② Initiation/referral
- ③ Follow-up
- ④ Outcomes

1 Identify patient: Is PrEP right for you?

- Provide PrEP and PEP education to every sexually active adult and adolescent, as well as those planning to be sexually active.
- Ask and explore and listen. What do you do currently to take care of your sexual health? How would you describe your current risk of acquiring HIV?
- How would taking a pill every day fit/not fit into your life?

1 Identify patient: Is PrEP right for you?

- Managing side effects
- Adherence strategies: link to other habit (brushing teeth), alarm, pill box
- Will you disclose your PrEP use to friends, family, sex partners?
- What if I want to stop PrEP?
- Access and financing: how to pay for PrEP (insured or uninsured)

② Initiation/referral

- Same-day initiation. Referrals: as fast as possible.
- HIV negative result as close as possible to PrEP initiation, no longer than 7 days in advance.
- Clinician will do thorough sexual history to determine if recent HIV acquisition is possible.
- Provide **PEP** education.

HIV testing technology

- Rapid/point-of-care 2nd or 3rd generation HIV antibody tests: **window period = 4 weeks**
- Rapid/point-of-care 4th generation HIV antigen and antibody test: **window period = 3 weeks**
- Lab-based 2nd, 3rd, 4th generation tests: **window periods = 3-4 weeks** (see above)
- HIV RNA/viral load test: **window period = 2 weeks**

What HIV testing is available at your agency or in your jurisdiction?

3 Follow-up

- Patient returns every three months for follow-up testing and new prescription.
- Navigator provides access and benefits counseling, other assistance as needed.
- Express visits: nonclinician and/or televisits and self-testing for asymptomatic patients.

4 Outcomes

- Person continues on PrEP without interruption as long as desired/needed.
- Person stops PrEP and uses another preferred HIV prevention strategy.
- **Person remains free of HIV.**

PrEP Financing Essentials

Scenario #2: Zachary

- 35yo, identifies as Latinx, cisgender male, gay. Was employed in IT dept of law firm until 3 months ago when he lost his job because of not showing up for work. Insured through COBRA.
- Zachary has been on PrEP for ~3 years. Almost all sexual activity during that time was PnP/chem sex. He just completed an outpatient rehab program. He stopped having sex and taking PrEP when he entered rehab.
- He is here for HIV/STI testing. He tells you he is “really disappointed” in himself and that now he “needs to focus on staying sober and getting a job and getting my life together.” He tells you he plans to be celibate for 6 months and doesn’t want to take PrEP because he thinks it will be a trigger to hooking up and relapsing.

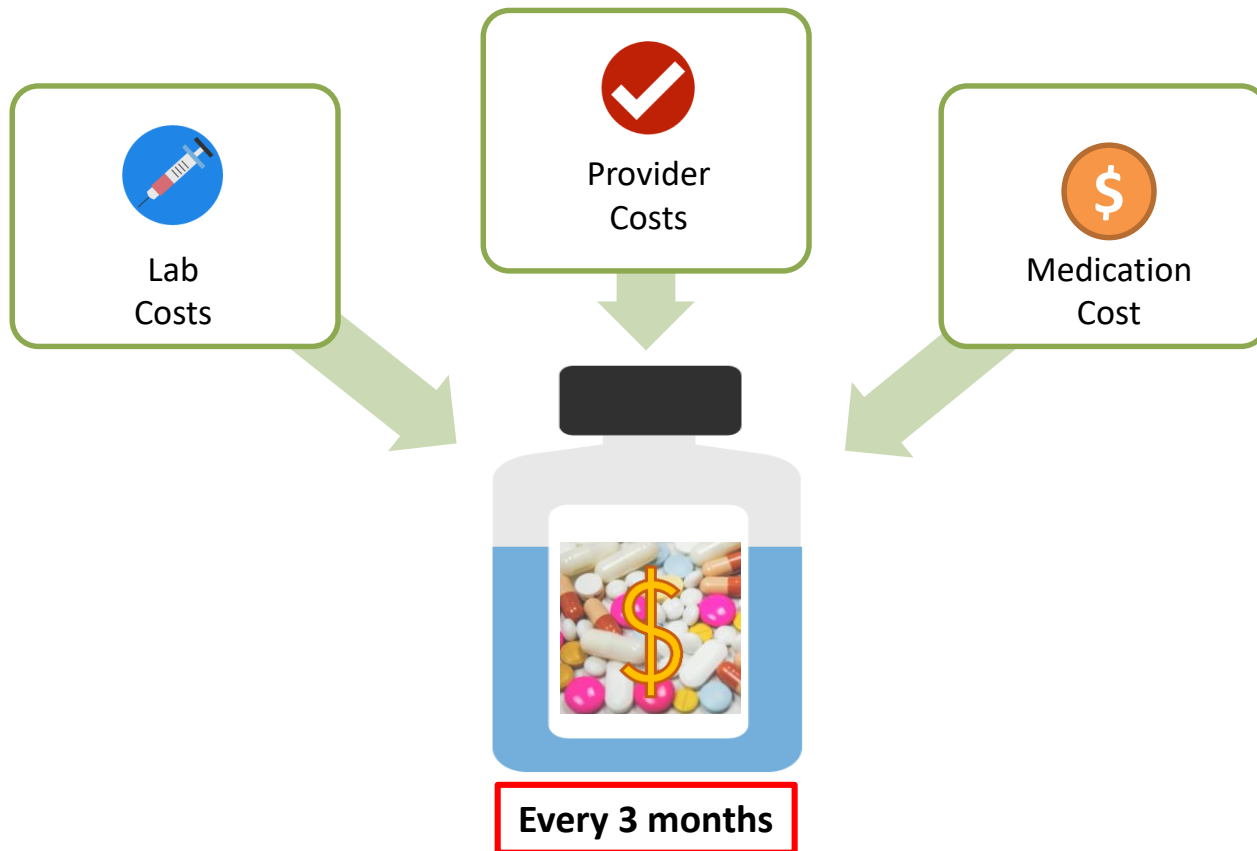
PrEP Financing Essentials

Question #2: How would you proceed with Zachary (check all that apply)?

- ☐ Ask Zachary if he'd like to talk about his concerns about relapsing.
- ☐ Ask to Zachary if you can contact his social worker or counselor to come up with a plan to keep Zachary on PrEP.
- ☐ Explore the pros and cons of staying on PrEP versus stopping PrEP.
- ☐ Encourage Zachary to accept a new PrEP prescription, just in case he needs it.
- ☐ Provide PEP information, if Zachary doesn't already know about it and how to get it.

PrEP Financing Essentials

The 3 Costs of PrEP



PrEP medication cost updates from 2021

- As of April 1, 2021, multiple generics for TDF/FTC have entered the market and driven costs down tremendously.
- Monthly cost may range from \$30 to \$1,000+.
- Most private insurance plans in Nevada cover generic TDF/FTC for PrEP.
- Pharmacies are proactive in switching patients to generic, and most private plans now require it. There is no manufacturer coupon for generics.

Generics on the Market

- **As of April 1, 2021, these generic versions of TDF/FTC were available:**
 - Teva Pharmaceuticals USA
 - Amneal Pharmaceuticals
 - Aurobindo Pharma USA
 - Macleods Pharmaceuticals
 - Mylan Pharmaceuticals
 - Zydus Pharmaceuticals
 - CIPLA LTD
 - Avkare, inc
- All have AB bioequivalence
 - AB bioequivalence indicates that pharmacies can switch patients from the brand-name drug to the generic therapeutic equivalent.

PrEP Financing Essentials

Uninsured: [Gileadadvancingaccess.com](https://www.gileadadvancingaccess.com)

Gilead Advancing Access Patient Assistance Program (PAP) for Truvada and Descovy.

Eligibility

- U.S. address on application
- Income \leq 5xFPL or \$64,400). May require verification
- Eligibility period/renewal after 12 months

iAssist: <https://advancingaccess.iassist.com/login>

Prescribing Information

[← Back to services](#)

[Collapse All Panels](#) | [Expand All Panels](#)

test tes

Male • 01/01/1940 • Age: 81

- ☐ Patient Information
- ☐ Patient Consent
- ☐ Prescriber Information
- ☐ Insurance
- ☐ Financial Assistance

[Save as Draft](#)

[Review](#)

^ Patient Information

☐ Not Started

Patient Name

test tes

* Address Line 1

SSN (Last 4)

Address Line 2

Medication

TRUVADA®

* Zip

* Prescribed for

- ☐ Treatment
- ☐ PrEP/Prevention

* City

* State

* Phone Number

☐ By clicking this check box, the patient acknowledges that they do NOT want to receive correspondence via U.S. mail from Advancing Access. This includes, but not limited to approval/denial letters for the patient assistance program, reminder letters for re-enrollment periods, etc. If you click this box, all communication to the patient will be via phone.

[Save Patient Information](#)

Uninsured

- How will patient (or provider) pay for office visits and lab work?
- Patient Advocate Foundation (copays.org/diseases/hiv-aids-and-prevention): up to \$7500/year, earn \leq \$51,520 (4xFPL)
- Minimum lab testing: HIV/creatinine/HBsAg at initiation; HIV every 3 months, creatinine every 3-12 months.

READY, SET, PrEP



for uninsured
>500% FPL

- Federally funded, currently administered by Trial Card
- Any age, income >500% FPL, no insurance coverage for PrEP
- <https://www.getyourprep.com/>
- [Link to iAssist log-in](#) (interface very similar to Gilead AA, you can use same log-in associated with the prescriber)

Insured: Nevada Medicaid

- **All Nevada Medicaid plans cover generic TDF/FTC for PrEP without a prior authorization (PA).** None cover the brand name. However, the patient has the right to appeal the denial of the brand name by calling member services.
- 3 of the 5 plans (Standard Medicaid (FFS), Silver Summit, and Molina Health) cover Descovy without a PA.
- Health Plan of NV and Anthem Medicaid require PA, but are almost always covered with documentation of intolerance or contraindication. Otherwise, it will be denied; citing step therapy required.
- PA approvals are usually good for 1 year.
- If patients happen to have HPN or Anthem Medicaid, they can call Medicaid directly to switch to a health plan that does offer coverage of Descovy.

PrEP Financing Essentials

Insured: Private insurance: some important terms

- Premium: amount person pays per month for insurance coverage.
- Deductible: amount person pays before insurance covers
- Copay (\$) or coinsurance (%): amount person pays for meds, visits after meeting deductible
- Maximum yearly out-of-pocket: the most person has to pay for all meds, services
- Prior authorization: permission from insurance company before it will pay for meds, services. Varies by insurer.
- Mail order pharmacy: required by some plans

Insured: Private insurance

(Employer-based; purchased independently or through Affordable Care Act)

- Bronze plans: high deductible, high copay (low premiums)
- Silver, gold, platinum plans: lower deductibles, lower copays (higher premiums)

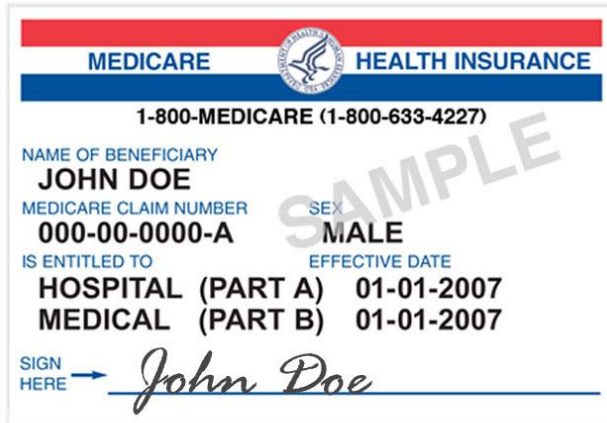
Insured: copay assistance programs

- Gileadcopay.com: \$7200/year, no eligibility requirements
- Patient Advocate Foundation (copays.org/diseases/hiv-aids-and-prevention): up to \$7500/year, earn $\leq \$51,520$ (4xFPL)
- Patient Access Network (currently funded only for Medicare patients) (Panfoundation.org): up to \$5000/year, earn $\leq \$51,520$ (4xFPL)

PrEP Financing Essentials

Parts A and B

Current Medicare Card



MEDICARE HEALTH INSURANCE
1-800-MEDICARE (1-800-633-4227)

NAME OF BENEFICIARY
JOHN DOE

MEDICARE CLAIM NUMBER
000-00-0000-A

SEX
MALE

IS ENTITLED TO
HOSPITAL (PART A) **01-01-2007**
MEDICAL (PART B) **01-01-2007**

SIGN HERE → John Doe

New Medicare Card (coming in 2018)



MEDICARE HEALTH INSURANCE

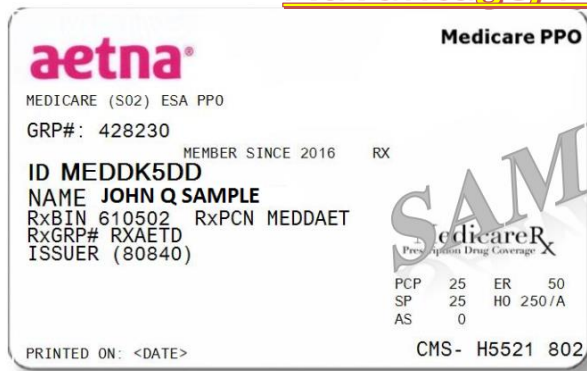
Name/Nombre
JOHN L SMITH

Medicare Number/Número de Medicare
1EG4-TE5-MK72

Entitled to/Con derecho a
HOSPITAL (PART A)
MEDICAL (PART B)

Coverage starts/Cobertura empieza
03-01-2016
03-01-2016

Advantage/Part C/Part D



aetna Medicare PPO

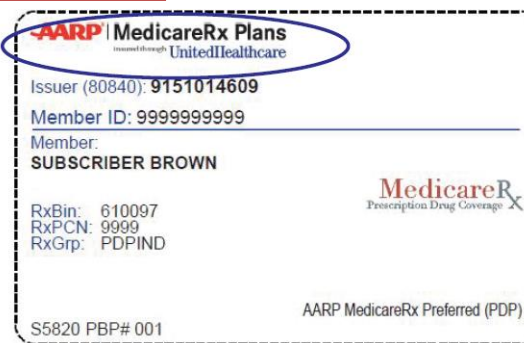
MEDICARE (S02) ESA PPO
GRP#: 428230

MEMBER SINCE 2016 RX

ID MEDDK5DD
NAME **JOHN Q SAMPLE**
RxBIN 610502 RxPCN MEDDAET
RxGRP# RXAETD
ISSUER (80840)

PCP 25 ER 50
SP 25 HO 250/A
AS 0

PRINTED ON: <DATE> CMS- H5521 802



AARP MedicareRx Plans
UnitedHealthcare

Issuer (80840): **9151014609**

Member ID: **9999999999**

Member:
SUBSCRIBER BROWN

RxBin: 610097
RxPCN: 9999
RxGrp: PDPIND

S5820 PBP# 001

AARP MedicareRx Preferred (PDP)

Medicare tips

- If has Rx coverage person must meet deductible (typically \$600/yr). After, person pays the 25% co-insurance (~\$10 at a pharmacy with lowest generic TDF/FTC prices)
- If no Rx coverage apply for Gilead AA or Ready, Set, PrEP based on income eligibility and Rx branded Truvada or Descovy

Veterans Administration (VA)



Refer to VA – other providers cannot even Rx!

If all else fails...

- Prescribe generic TDF/FTC; patient pays out of pocket (~\$30+/month)
- Or, if the patient does not want an Rx on file in the US healthcare system, advise them that they can import from overseas
 - <https://www.iwantprepnnow.co.uk/>
- Consider a telemedicine provider that picks up the tab for labs/provider costs
 - <https://pleaseprepme.org/online-providers>

Long-Acting Injectable PrEP

Uninsured individuals

[https://www.viivconnect.com/content/dam/cf-viiv/viiv-connect/master/pdf/APRETUDE Enrollment Form.pdf](https://www.viivconnect.com/content/dam/cf-viiv/viiv-connect/master/pdf/APRETUDE_Enrollment_Form.pdf)

- PAP eligibility criteria: US resident, income \leq 500% US fed poverty line, no ins/pharm coverage; if Medicare: met \$600/yr out-of-pocket limit
- Best to complete by hand and fax to ViiV Connect; portal not easy to navigate.
- Under most optimistic timeline, application approved in 1-2 days; ViiV contacts provider to arrange shipment from specialty pharmacy, likely received in 2-4 days. Could give injection within a week if all goes well.

Long-Acting Injectable PrEP

Insured individuals

- Navigators (or patients) need to verify coverage with insurance provider – varies by company/state. May require prior authorization and/or proof of medical necessity.
- Medication will be shipped to provider from specialty pharmacy associated with insurance provider.
- Process probably longer than a week for patient to receive injection.
- Copay card: Up to \$7850/year for out-of-pocket expenses. May also cover associated care costs (visit, labs), but depends on whether insurance provider classifies injectable PrEP as a pharmaceutical or a medical benefit.

Long-Acting Injectable PrEP

Still lots of questions...

- HIV testing window? If cannot give injection within 7 days, retest? What about RNA test recommendation/requirement?
- Will injectable PrEP address gaps in PrEP access and retention?
- Stocking Apretude not feasible in most settings. 340B price + ~\$2800/dose
- Providers/navigators should contact their **field reimbursement manager** for assistance with ViiV Connect and other access matters.
- ViiV sponsoring implementation studies.
- <https://apretudehcp.com/>

What are my role and responsibilities to assist clients/patients with insurance navigation?



30/30 Clinical history

Switch page

Initial questions

PMH&CTD

STD hx

Partners

Women

Pap results

Risk factors

Notes

Photos

Partner Totals (three months only)

Male Female TGF TGM New

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Sexual Practices past 3 months

partners w/out condom:

Vaginal sex ☐ Yes ☐ NoAnal insertive ☒ Yes ☐ NoAnal receptive ☐ Yes ☒ NoPerformed oral sex on penis ☐ Yes ☒ NoReceived oral sex on penis ☐ Yes ☒ No

1

How long since sex with ...

Any partner		HIV+ (HIV- only)	
IDU partner		MSM (women only)	

Receptive anal intercourse in past 6 mo (male patients only) ☐ Yes ☐ No**PrEP Questions:**

ask all HIV- MSM and all HIV- trans persons who have sex with men; others asked PRN based on risk

Ever heard of PEP? ☐ Yes ☒ NoCurrently on PrEP? ☐ Yes ☒ NoEver heard of PrEP? ☒ Yes ☐ NoEver on PrEP? ☒ Yes ☐ No**Reason(s) not PrEP**☒ Prefer condoms☐ Awaiting enrollment☐ No insurance☐ Concerned about side effects☐ Do not want to take a pill every day

Other reasons:

☐ Not HIV high risk

CONTRAINDICATED

(click arrow to add)

**PrEP referral**☐ Accepted PrEP referral☐ Declined PrEP referral

Date: 7/27/17

☒ Allow changes

Save

Undo

Print

59/59 Clinical findings

Phone

Findings

History

Prescriptions Counseling F/U & Referrals Billing PrEP Express

PrEP enrollment data

Status: GETTING PREP FROM SFCC

Enrolled: 1/31/2019

Discharged:

Worker:

Strategy: DAILY

New Delete

Source of Truvada

☐ Private insurance ☐ On-line pharmacy ☐ Gilead PAP

☐ Medi-Cal ☐ Medicare ☐ HHS and Gilead

Eligibility expires:

Important reminders

date	reminder
01/26/17	take pills

Reminder:

New

Adherence

Current strategy: Doses missed past 7 days: Most recent sex act was covered by 2-1-1:

Future strategy: Doses missed past 30 days: Uncovered sex acts past 30 days:

How long since last took PrEP?

Since last HIV test, have there been 7+ days in a row without any PrEP?

Date: 11/24/20

☒ Allow changes

Save

Undo

Print

③ Follow-up



3 Follow-up

How are we managing our PrEP cohort of clients/patients?

- Visit reminders
- Contact for missed visits
- Contact for lost-to-follow
- How are we keeping track of all of this?

Seroconversions

- 18/1297 (1.4%) seroconverted after initiating PrEP at SF City Clinic
 - 2 were still enrolled in PrEP care
 - 7 had been lost to follow-up
 - 9 had stopped PrEP
- Median time to HIV diagnosis from discharge date = 190 days
- Race/ethnicity
 - 7 white (39%)
 - 6 Latino (33%)
 - 3 black (16%)
 - 2 Asian (11%)
- Mean age 29
- 6 were diagnosed with acute HIV infection
- 7 not SF residents

Stopping PrEP – Themes

- Cost, coverage and other logistics
 - Issues with patient assistance program
 - Insurance gap or change
 - “Too busy”
 - Difficulty picking up meds at pharmacy
- Change (or desired change) in sexual behavior
 - In relationship with HIV-negative partner
 - Didn’t think at risk
 - Trying to stop methamphetamine and decrease sexual activity
 - Trying to have fewer partners

What is PEP?

- PEP (nPEP) = Post-Exposure Prophylaxis (to HIV)
- HIV prevention strategy for individuals exposed or with possible exposure to HIV.
- Initiated ASAP, no later than within 72 hours of exposure.
- Oral medication taken for 28 days.
- <https://www.cdc.gov/hiv/basics/pep.html>

Where do people go for PEP access and counseling?

- Do you provide PEP? If not, where is PEP available in your jurisdiction?
- Do you have referral and other PEP information available for patients?

Take a photo

Are you worried that you may have been exposed to HIV recently? You may need **PEP**.

What is PEP?

- PEP (nPEP) = Post-Exposure Prophylaxis (to HIV)
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- Oral medication taken for 28 days.
- <https://www.cdc.gov/hiv/basics/pep.html>

Where can I get PEP?

- Contact your doctor.
- Call or go to a clinic (insert name(s), hours, etc, for your and/or other clinics.
- Go to an emergency room.

PEP

<https://www.cdc.gov/hiv/risk/pep/index.html>

Uninsured

Truvada or Stribild: [Gileadadvancingaccess.com](https://www.gileadadvancingaccess.com)

Tivicay: [ViiVConnect.com](https://www.viivconnect.com)

Insured

Truvada or Stribild: [Gileadcopay.com](https://www.gileadcopay.com)

Tivicay: mysupportcard.com/get-savings-card.html

Isentress: [activatethecard.com/7387/#](https://www.activatethecard.com/7387/#) (mail order?)

Nevada Medicaid

All plans cover PEP medications without PA

PrEP and PEP Navigation Essentials

PEP → PrEP

- Should there be a gap between the completion of PEP and the initiation of PrEP to confirm HIV neg status?

4 Outcomes

Person plays an active role in taking care of their own sexual health.



Better quality of life.



Scenario #3: Anastasia (she/her/hers)

- 31yo, identifies as Latina, cisgender female, straight. Works with cousin in housecleaning service. Uninsured.
- Lives with boyfriend of 2 yrs, Mathieu (he/him), 29yo, identifies as mixed race, cisgender male. Mathieu told Anastasia he was HIV-neg when they met, but to her knowledge he has not been tested since. Anastasia thinks Mathieu might have some sex partners outside of their relationship, perhaps other men, based on a history he disclosed to her when they met. Anastasia and Mathieu do not use condoms for intercourse. She expresses concern to you about getting HIV or STIs.
- When you tell Anastasia about PrEP, she is interested, but she worries about keeping it secret from Matthieu and about him “freaking” out if he were to find out.

PrEP Financing Essentials

Question #3: How would you proceed with Tad (check all that apply)?

- ☐ Ask Anastasia if she and Mathieu have talked about sex recently.
- ☐ Tell Anastasia she should talk frankly to Mathieu about her concerns.
- ☐ Screen for domestic violence.
- ☐ Explore how Anastasia might feel comfortable taking PrEP.
- ☐ Talk with Anastasia about her options for paying for PrEP.
- ☐ If Anastasia wants, write her a prescription for TAF/FTC (Descovy).
- ☐ If Anastasia wants, write her a prescription for TDF/FTC (Truvada or generic).
- ☐ Sign Anastasia up for patient assistance program.
- ☐ Sign Anastasia up for copay card.

Envision

our roles in ending the HIV epidemic.

PrEP Navigation Essentials

Questions? Comments?

Thank you!

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