

Pre-Exposure Prophylaxis (PrEP) Toolkit for Community Based Organizations (CBOs)

To assist community based organizations in their efforts to promote PrEP, the New York State Department of Health is sharing this toolkit that outlines action steps and resources. For more information, contact the AIDS Institute's Office of the Medical Director at 518-474-3045

New York State's Plan to End the AIDS Epidemic: Pillar 3

Facilitate access to PrEP for high-risk persons to keep them HIV negative.

The New York State Department of Health (NYSDOH) AIDS Institute urges clinical providers and prevention programs to view PrEP as part of a comprehensive prevention plan for individuals, including adolescents, who are not living with HIV and are at high risk for acquiring HIV and have adequate renal function. This includes people who are having unprotected vaginal or anal intercourse with partners whose HIV status is unknown or partners who are living with HIV but not virally suppressed. People who have a history of sexually transmitted infection, who inject drugs and people who combine sex and certain types of substances are also candidates for PrEP. A complete list of persons who may benefit from PrEP is available at [PrEP to Prevent HIV and Promote Sexual Health](#).

Action Steps for Community Based Organizations

<i>At the Organizational Level</i>	<i>At the Programmatic Level</i>
✓ Agency leadership and governing board should be well informed about PrEP	✓ Integrate messages about PrEP into all prevention services
✓ Train your staff about PrEP	✓ Provide community presentations on PrEP
✓ Highlight PrEP on your agency website	✓ Integrate messages about PrEP into HIV testing services
✓ Assist clients with accessing financial assistance for PrEP	✓ As appropriate, link high risk, HIV- clients to providers who prescribe PrEP
✓ Provide links on your agency's website to NY PrEP campaign at www.prepforsex.org or text message service reached by texting GETPREP to 69866	✓ Include PrEP in your agency's social media Messaging using the AIDS Institute PrEP Social Media Toolkit* see next page
✓ Be familiar with medical providers who prescribe PrEP in your region by reviewing the NYSDOH Voluntary Directory or PrEP/PEP providers at: https://www.health.ny.gov/diseases/aids/geral/prep/prep_index.htm	✓ Establish linkage agreements with medical providers to provide their PrEP patients with prevention and supportive services
✓ Take an active role encouraging medical providers in the region to prescribe PrEP	✓ Partner with CBOs, local health departments and DOH regional offices to link high risk HIV- individuals to PrEP services
✓ Address community misconceptions about PrEP	✓ Offer support services and/or education for clients on PrEP
	✓ Create an environment where clients can openly consider if PrEP is an option for them

AIDS Institute PrEP Social Media Toolkit

In June 2019, the AIDS Institute released a PrEP Social Media Toolkit for use by community partners and stakeholders. The toolkit features a diverse panel of models and addresses three key topics related to accessing PrEP: Is PrEP Right for Me? Where can I get PrEP? and What are my payment options? The toolkit provides easy to use digital materials which are in English and Spanish. The materials are sized to match various social media platforms, such as Facebook, Twitter and Instagram. For more information about this campaign and to sign up to participate, contact 518-474-3045 or email hivet@health.ny.gov



Check out the toolkit at: https://www.health.ny.gov/diseases/aids/general/prep/social_media_toolkit.htm

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New Developments in PrEP for Adolescents:

Capacity to Consent

A 2017 amendment to the New York Codes, Rules and Regulations (NYCRR) grants minors the capacity to consent to PrEP, post-exposure prophylaxis (PEP) and HIV treatment without parental/guardian involvement, bringing capacity to consent to HIV-related services on a par with capacity to consent to other STD prevention and care. Clinical providers may, over time, discuss with their minor patients opportunities for parental or guardian involvement in these decisions, including exploring with the young person the potential benefits of parental or guardian involvement. However, decisions about the involvement of a young person's parent or guardian must be left to the young person. Clinical providers should maintain a high level of sensitivity to the concerns of the young person regarding potential negative consequences of involvement of a parent or guardian. Discussions about whether to involve a parent or guardian should never result in a delay in starting HIV prevention or treatment services.

For more information review the document titled **HIV Testing, Reporting and Confidentiality in New York State, 2017-18 Update: Fact Sheet and Frequently Asked Questions** which can be found at <https://www.health.ny.gov/diseases/aids/providers/testing/>.

Clinical Issues

On May 15, 2018, the U.S. Food and Drug Administration (FDA) approved TDF/FCT (Truvada) use for adolescents weighing at least 35 kg (~77 lb) at high risk of acquiring HIV. New York State Clinical Guidelines state that clinicians should recommend PrEP for individuals, including adolescents*, who do not have but are high risk of acquiring HIV and have adequate renal function. (A1)

See NYSDOH AI: [Forum on PrEP for Adolescents: Successes, Challenges & Opportunities](#) for an extensive discussion of considerations for PrEP in adolescents.

Tools and Resources:

The following tools and resources can be found in Appendix 1 or on the NYS Department of Health PrEP Webpage at: https://www.health.ny.gov/diseases/aids/general/prep/prep_index.htm

Information for Individuals Considering PrEP

1. PrEP/PEP Voluntary Provider Directory to locate providers in your area
2. Frequently Asked Questions for Consumers
3. Link to www.prepforsex.org “HIV Prevention Just Got Easier” Public Campaign
4. PrEP Yourself Against HIV – Consumer poster and brochure in English and Spanish
5. PrEP Patient Assistance Program – financial assistance to cover health care costs of PrEP
6. Payment Options for PrEP – summary document
7. Link to the Drug Manufacturer’s Patient Assistance Programs

Information and Resources for Clinical Providers and Support Services Providers

1. PrEP-AP for Providers: Information about How Providers can Enroll in PrEP-AP
2. Link to Clinical Education Programs for PrEP Providers – www.ceitraining.org
3. What Support Services Providers Should Know About PrEP: Fact Sheet
4. For information about trainings on PrEP for Clinical and Non-Clinical Providers visit www.hivtrainingny.org

New York City Department of Health and Mental Hygiene PrEP Webpage:

<https://www1.nyc.gov/site/doh/health/health-topics/prep-pep-resources.page>

Includes information for consumers, FAQs, link to a directory of NYC providers, checklist for clinics preparing to offer PrEP and other helpful materials.

NYS PrEP Clinical Guidelines:

New York State Clinical Guidelines

<https://www.hivguidelines.org/prep-for-prevention/>

PrEP Checklists and Management Tools

https://www.hivguidelines.org/prep-for-prevention/prep/#tab_13

US Public Health Service Clinical Practice Guidelines:

Pre-exposure Prophylaxis for the Prevention of HIV in the United States: A Clinical Practice Guideline 2017: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

Taking a Sexual History - Palm Card:

<https://www1.nyc.gov/assets/doh/downloads/pdf/csi/csi-prep-pep-sex-history.pdf>

NYS PrEP Consumer Education Materials Order Form:

https://www.health.ny.gov/forms/order_forms/prep.htm

SAMPLE HIV/STD/HCV Risk Screening Tool

Adapted from Planned Parenthood of NYC Brief PrEP Screening

PrEP is a daily pill for HIV-negative people. It protects you in case you are exposed to HIV in the future. If you say yes to any of the questions below, PrEP might be right for you.

In the last 6 months, did you:

- Have sex without condoms with a person whose HIV status is unknown, who has untreated HIV or who is not HIV undetectable?
- Have a sexually transmitted infection (an “STD”), such as gonorrhea, syphilis, or herpes?
- Have sex while drunk or high?
- Have sex for something you needed (such as housing, money, drugs)?
- Share needles or injection supplies?

In the last 6 months, have you had a sexual partner who:

- Refused to use condoms?
- Made you have sex when you did not want to?
- Had sex with anyone besides you?
- Injected drugs with a needle?
- Is living with HIV and has an undetectable viral load but you would like additional protection?

If you answered yes to any of the questions, ask a health care provider about an HIV test and whether PrEP might be for you.

Note to Provider Conducting the Screening: Considerations: PrEP and PEP

Reference: https://www.hivguidelines.org/prep-for-prevention/prep/#tab_2

Candidates who should be offered PrEP include individuals who:

- Engage in condomless sex with partners whose HIV status is unknown, or who have untreated HIV, or who have unsuppressed virus while on treatment for HIV.
 - Are attempting to conceive with a partner who has HIV.
 - Are at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus.
 - Have, or are involved with partners who may have, multiple or anonymous sex partners.
 - Engage in sexual activity at parties and other high-risk venues, or have sex partners who do so.
 - Are involved, or have partners who may be involved, in transactional sex (i.e., sex for money, drugs, food, or housing), including commercial sex workers and their clients.
 - Have been diagnosed with at least 1 bacterial sexually transmitted infection (STI) in the previous 12 months
 - Report recreational use of mood-altering substances during sex, including but not limited to alcohol, methamphetamine, cocaine, ecstasy, and gamma hydroxybutyrate.
 - Report injecting substances or having sex partners who inject substances, including illicit drugs, hormones, or silicone.
 - Are receiving non-occupational post-exposure prophylaxis (nPEP) and anticipate ongoing risk or have used multiple courses of nPEP
 - Request the protection of PrEP even if their sex partners have an undetectable HIV viral load
 - Self-identify as being at risk without disclosing specific risk behaviors.
 - Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.
- **Do not withhold PrEP from candidates who:**
- Are pregnant or planning a pregnancy.
 - Use other risk-reduction practices inconsistently, including condoms.
 - Report substance use.
 - Have mental health disorders, including those with serious persistent mental illness.
 - Report intimate partner violence.
 - Have unstable housing or limited social support.
 - Report a recent STI.
 - Request PrEP even in they have a partner living with HIV with an undetectable viral load.

PEP: Post exposure prophylaxis should be recommended and a referral for immediate medical attention should be made when an individual reports a high risk exposure within the past 72 hours. Situations that may prompt an immediate referral for PEP include:

- Unprotected (condomless) receptive or insertive vaginal or anal intercourse with an HIV positive partner or a partner whose status was unknown, including intercourse that involved condom slippage or breakage
- Unsafe needle-sharing;
- Injuries with exposure to blood or other potentially infected fluids from a source known to be HIV-infected or HIV status is unknown (including needlesticks with a hollow-bore needle, human bites, accidents)

NOTE: For persons presenting with wounds or needlestick injuries, the site should be washed with soap and water, avoiding irritation of the skin. The wound should not be “milked” or squeezed. Squeezing the wound may promote hyperemia and inflammation at the wound site, potentially increasing systemic exposure to HIV if present in the contaminating fluid.

- Lower risk exposures that require evaluation by a clinical provider on a case by case basis include:
 - Oral-vaginal contact (receptive and insertive)
 - Oral-anal contact (receptive and insertive)
 - Receptive penile-oral contact with or without ejaculation
 - Insertive penile-oral contact with or without ejaculation

NOTE: The level of risk in these situations increases with presence of blood, genital ulcers, an STD or non-intact skin or mucus membrane

Key Messages About PrEP

Describing PrEP

PrEP is an individualized plan to prevent HIV and promote sexual health. It involves taking the medication to prevent HIV. It is safe and effective. PrEP helps keep you healthy with regular screening for HIV and STIs.

Effectiveness of PrEP

PrEP is effective at preventing HIV. It is important to take the medicine as prescribed by your provider for it to be most effective.

Addressing Side Effects

Side effects don't usually cause people to stop taking PrEP. You may have mild side effects. If you have them, they are usually short term. You should tell your provider about any side effects. The provider can work with you to address any side effects that are bothering you.

Addressing Cost Issues

There are many resources to help make sure PrEP is affordable to you. There are resources to pay for the medication, to pay for your health appointments and testing, and help to pay for any co-pays you cannot afford. Information is available from a support provider or at

https://www.health.ny.gov/diseases/aids/general/prep/docs/prep_payment_options.pdf

PrEP, Stigma and Confidentiality

Your health is worth protecting. If you are concerned about what others may think about you because you are taking PrEP, just remember, you don't have to tell anyone you are taking PrEP.

Having a Partner who is Living with HIV

If you are HIV negative and have sexual partners who are living with HIV, you can consider PrEP when making decisions about HIV prevention. It is important to be aware that a person living with HIV who has had an undetectable viral load for at least six months has no risk of passing HIV to a partner through sex. If this is the case, PrEP is not needed but may be considered as an option to provide additional protection. If the person living with HIV is not on HIV treatment or does not have an undetectable viral load, then PrEP is recommended along with condoms to prevent the HIV negative person from getting HIV and to protect both partners from STIs.

How Long to Take PrEP

It's up to you how long you take PrEP. You can get up to three months' supply at a time. It's good to protect yourself and if things change, like you get into a steady relationship where you both test negative, you might be ready to stop PrEP. Sometimes, people are ready to use condoms consistently and may choose to stop PrEP. Condoms also provide protection against STIs.

Talking with Your Provider About PrEP

It's important to be open with your provider about your experience with PrEP, like how often you take the medicine, if you are thinking about stopping PrEP, side effects and any other questions or concerns you may have. If you are ready to stop PrEP, talk with the provider about how to do that safely.

MI Protocol for Discussing PrEP with Clients at High Risk for HIV Acquisition

The flow chart below shows how a provider might progress through a counseling session about PrEP using Motivational Interviewing as a guide. Follow the arrows based on client responses.

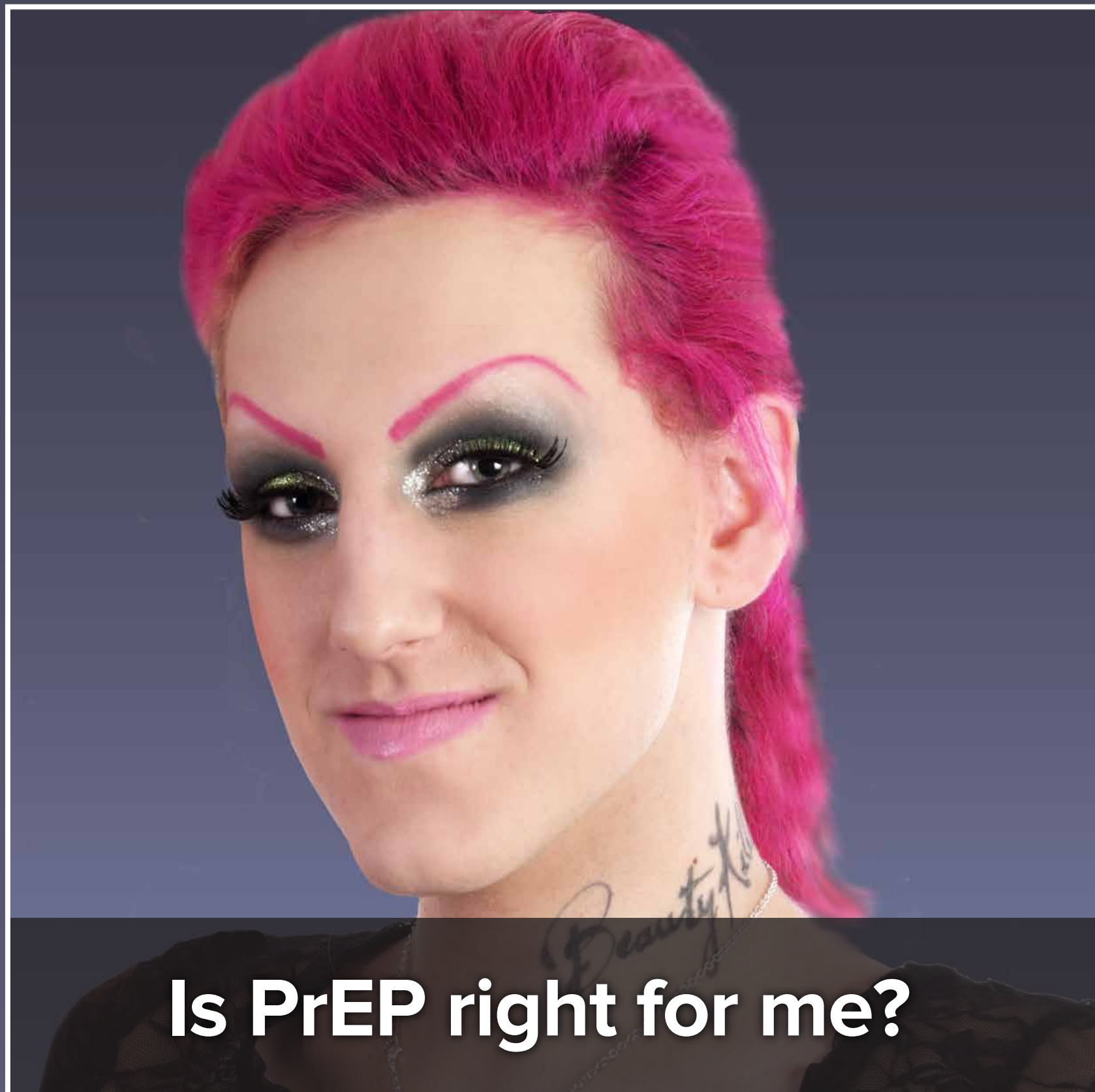
“Based on the risks that you shared (e.g. condomless anal intercourse; having an STI; sex with an HIV positive partner who is not virally suppressed; use of PEP more than once, or other risk), PrEP could be a good HIV prevention tool for you. I can share with you information about how PrEP medication works, where you can get it and assistance that makes PrEP affordable for all. Would you be interested in hearing more about PrEP?”

<i>Client expresses interest in PrEP.</i>	<i>Client is interested but identifies a barrier or concern.</i>	<i>Client is strongly opposed to considering PrEP.</i>
↓	↓	↓
Your interest in PrEP really shows that you care about your health. PrEP is very effective when taken as prescribed. Most people have few or no side effects and there is assistance to make sure PrEP is affordable. What day/ time and location is best for you to have an appointment?	So, on the one hand, I hear you are interested in PrEP but you also have concerns. That is understandable. Many of my clients have had to weigh different pros and cons. Let’s take a few minutes to talk about what you think would be good about PrEP and what your concerns are.	Ok, I understand. (Reinforce a strength you observed.) You may be hearing more about PrEP in the future because more and more people are taking it. Let’s talk about other HIV prevention and harm reduction options that might work for you.

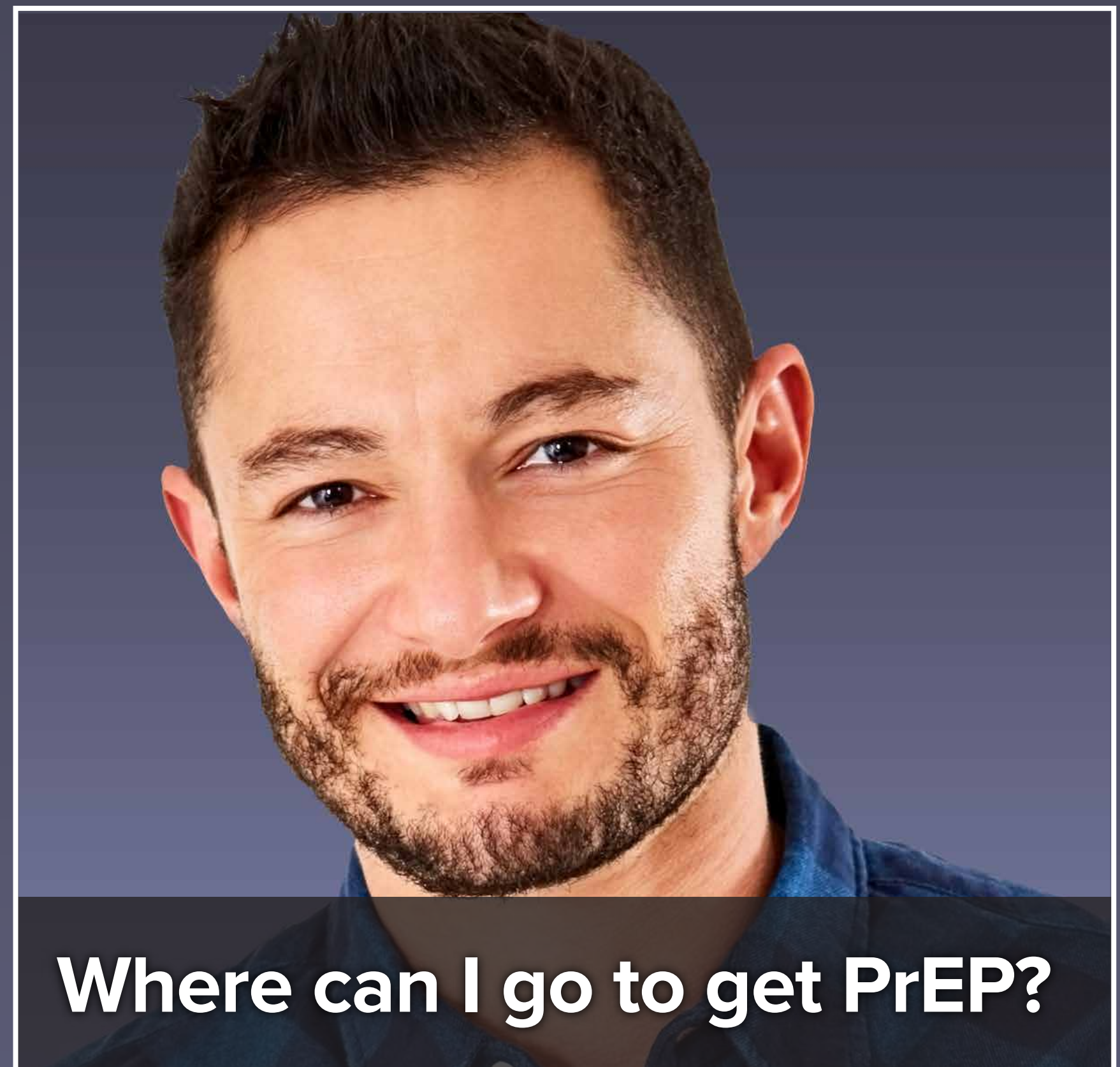
Exploring Common Concerns		
Side Effects	Cost	Stigma
<ul style="list-style-type: none"> - I hear your concern about side effects. In my experience with clients, most people have few or no side effects. - When a person does have side effects, they are usually short term and the provider can give other meds or strategies to minimize any discomfort. - How would you feel about PrEP if you knew that you might not even have side effects, or if you did, your provider would work with you to minimize them? 	<ul style="list-style-type: none"> - Many people are concerned about the cost of PrEP. - Costs include the medicine, appointments and labs. - Medicaid covers all the costs and so do health insurance plans. Financial assistance is also available from the drug manufacturer and a state program called PrEP-AP. - This agency is successful in getting help for everyone interested in PrEP. - If we can resolve all of your concerns about cost, would you be interested in an appointment for PrEP? 	<ul style="list-style-type: none"> - It seems like you are interested in PrEP but you don’t want others to judge you for it. - One good thing about PrEP is that you can take the medicine in private. No one else needs to know. - Attitudes about PrEP are changing as more people start using it. How would it feel if you were one of the people that helped your community overcome stigma around PrEP? - How might the future look if you do or don’t start PrEP?”
General Mistrust of Health Care and Health Care Providers/ Concerns in Communities of Color		
<ul style="list-style-type: none"> - I know it can be difficult to trust health care providers when you, or others you know, have had a past negative experience. What would you need in order to feel safe and in control? 		

HIV PrEP

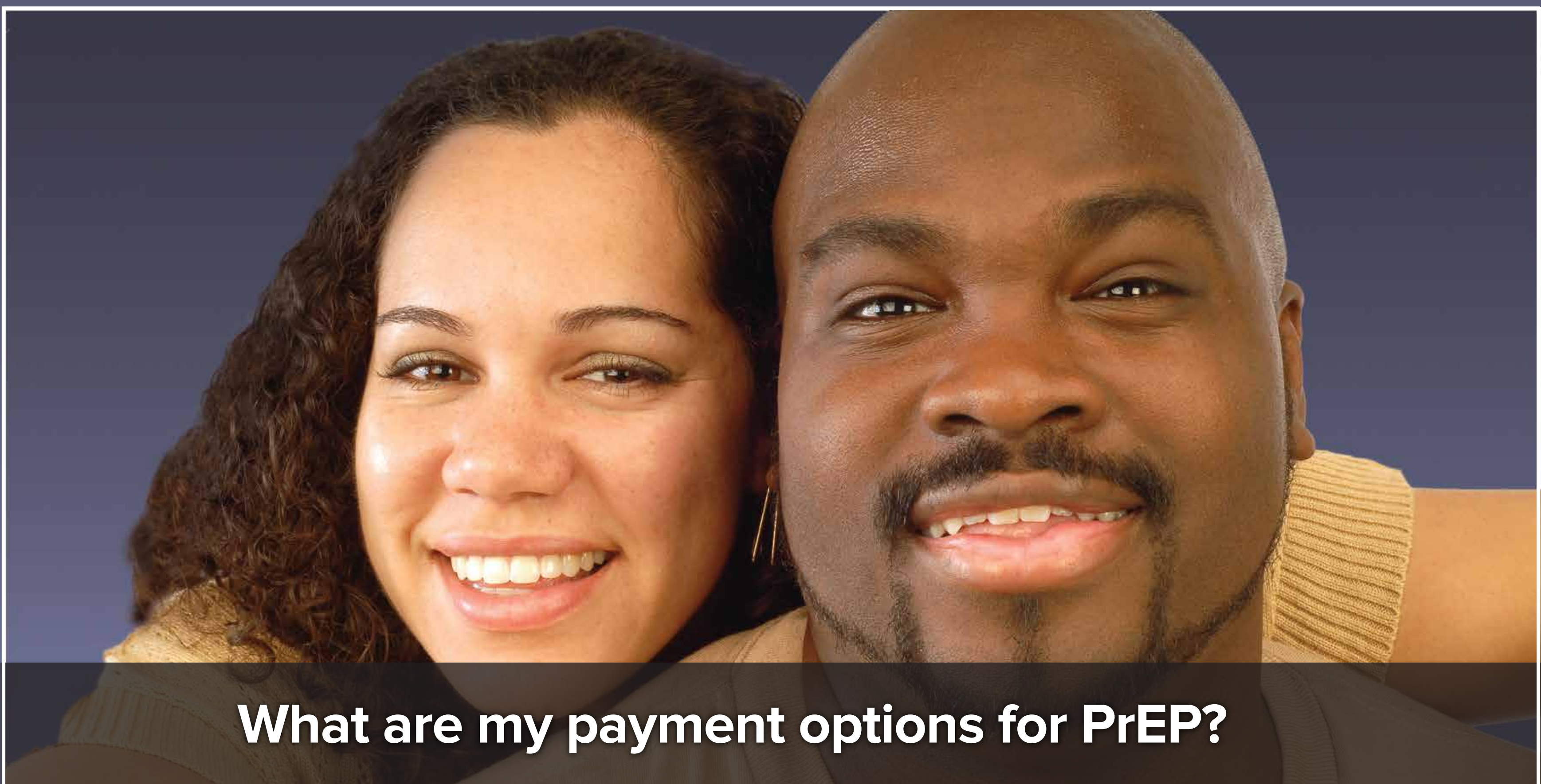
A Daily Pill Can Prevent HIV



Is PrEP right for me?



Where can I go to get PrEP?



What are my payment options for PrEP?

**Talk to a healthcare provider.
Ask about pre-exposure prophylaxis (PrEP).**

Text GetPrep (or PrEPahora in Spanish) to 69866 for an interactive conversation.

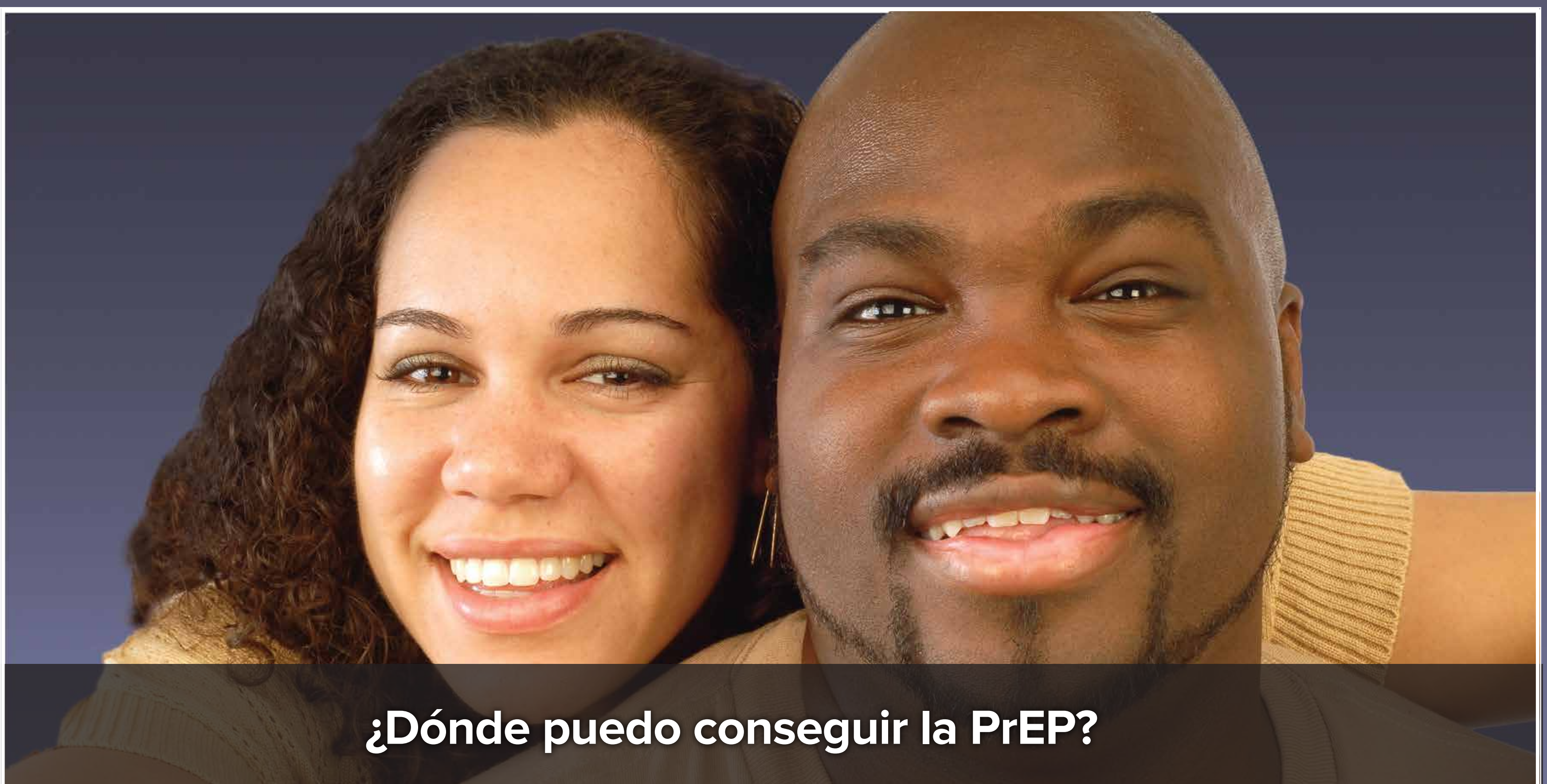
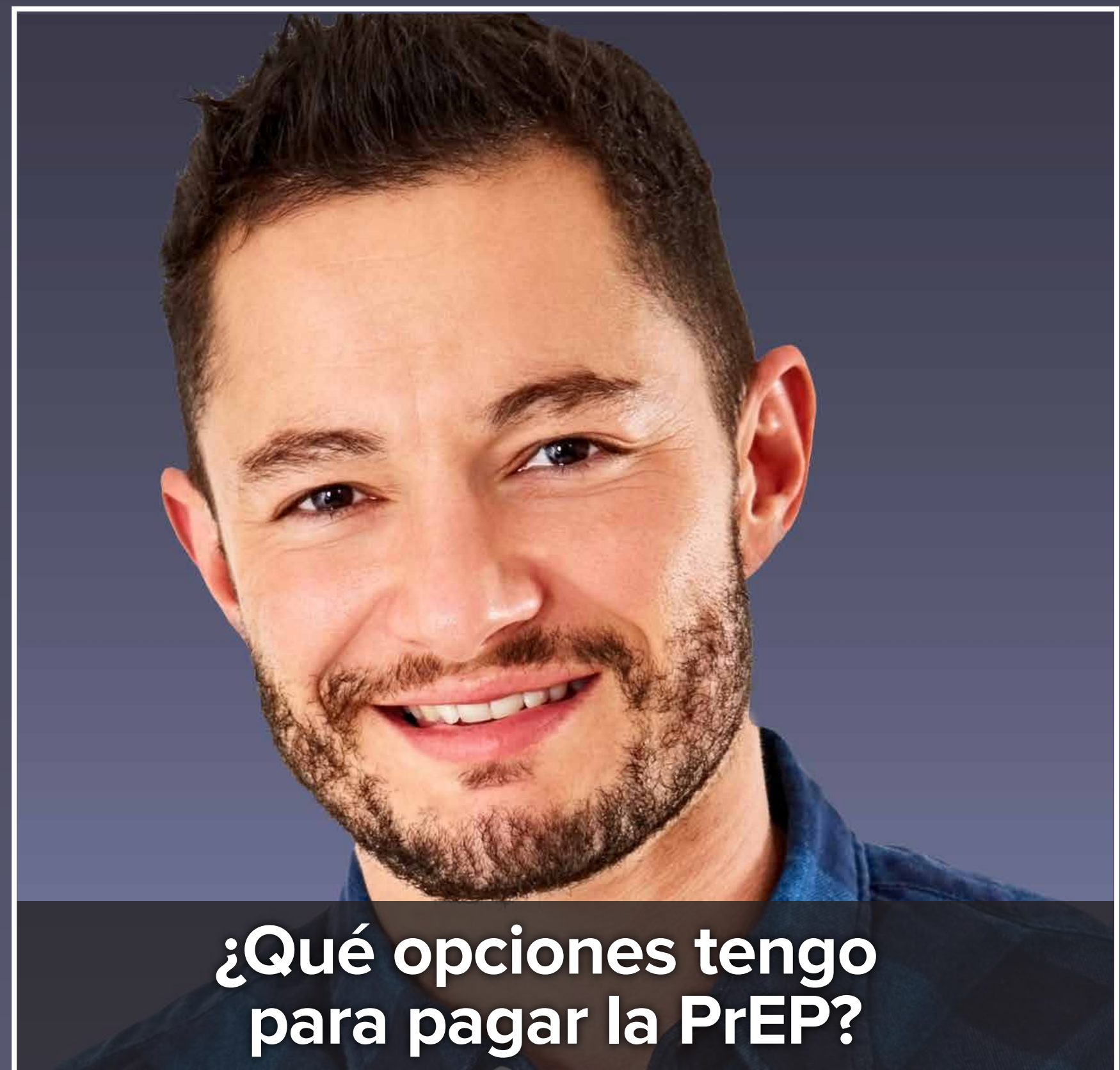
Visit prepforssex.org or call 1-800-541-AIDS for more information.



Department
of Health

PrEP PARA EL VIH

Un comprimido diario puede prevenir el VIH.



**Hable con un prestador de atención médica.
Consulte acerca de la profilaxis previa a la exposición
(PrEP, por sus siglas en inglés).**

Escriba un mensaje de texto con la palabra GetPrep (o PrEPahora para español)
al 69866 para tener una conversación interactiva.

Visite prepforsex.org o llame al 1-800-541-AIDS para obtener más información.

HIV Pre-exposure Prophylaxis (PrEP): Individualized HIV Prevention Frequently Asked Questions

1. Is it true that there is a medication that can PREVENT someone from getting HIV?

Yes. PrEP (short for HIV **P**re **E**xposure **P**rophylaxis) involves working with a healthcare provider to make an individualized plan to take medication to prevent HIV. Clinical trials have shown that PrEP is 99% effective at reducing sexual transmission of HIV. As of January 2019, the U.S. Food and Drug Administration (FDA) has approved two medications as PrEP for HIV: Truvada (tenofovir disoproxil fumarate 300 mg/emtricitabine 200 mg), and Descovy (tenofovir alafenamide 25 mg/emtricitabine 200 mg). Note: Descovy is not approved for use by cis-gender women.

Key Points About PrEP:

- PrEP medication is prescribed by a healthcare provider. People interested in PrEP can work with a healthcare provider to determine how PrEP can be tailored to their individual needs and circumstances.
- PrEP is only for people who are not living with HIV. HIV testing should be conducted before starting PrEP and repeated every three months to make sure the person is not living with HIV. Testing may be done by the healthcare provider or at a conveniently located community-based organization (CBO), healthcare facility or lab.
- Some people benefit from counseling and support for taking the medication regularly. If this is needed, the person can talk with the healthcare provider, a trusted CBO, a peer worker, or other provider.
- People at risk for HIV are also at risk for sexually transmitted infections (STIs). Counseling about using condoms to prevent STIs and periodic screening for STIs is important and may be provided by the healthcare provider, a trusted CBO, or other provider.

2. How often do I take the PrEP medication?

You and your healthcare provider can work together to decide the best way for you to use PrEP. There are two different ways that people take PrEP:

Daily PrEP: Daily PrEP involves people of any gender identity (cis-gender man, cis-gender woman or transgender man or woman) taking 1 pill once a day, every day. With daily PrEP, a person can feel protected from HIV whenever they have sex or inject substances. It is for people who have possible exposure to HIV on a frequent basis, or an unpredictable basis. An important benefit of daily PrEP is that the person is always protected and can establish a daily

habit of taking the medication. Daily PrEP with Truvada is the only method proven to be effective for cis-gender women and transgender men who have vaginal intercourse.

On-Demand PrEP: On-demand PrEP is only for cis-gender men who have sex with men (MSM). On-demand PrEP involves taking 2 pills, 2-24 hours before a possible sexual exposure to HIV and then continuing to take 1 pill each day until 2 days after their last possible sexual exposure. The only PrEP medication approved for on-demand use is Truvada. If a cis-gender MSM has a single possible exposure, they would take 2 pills, 2-24 hours before having sex and then would take 1 pill each day for 2 additional days. If a person had several possible exposures over the course of 2 or more days, the person would take 2 pills, 2-24 hours before the possible exposure, then 1 pill for each day they are having sex, and then 1 pill each day for 2 days after the last possible exposure. On-demand PrEP is for cis-gender MSM who have occasional risk for HIV that can be predicted at least 2 hours in advance. Cis-gender women, cis-gender men who have sex with women, people of trans experience, and people who share injection equipment should choose daily PrEP, not on-demand PrEP.

It is important to talk with your healthcare provider about whether daily PrEP or on-demand PrEP is right for you.

3. Is it OK to switch between daily PrEP and on-demand PrEP?

On-demand PrEP is only for cis-gender MSM. Other individuals are not eligible for on-demand PrEP because studies have not demonstrated that it is effective for other populations. Before switching from daily PrEP to on-demand PrEP, or vice versa, a cis-gender MSM should consult with their healthcare provider.

4. How often are medical appointments for PrEP?

People who want to take PrEP to prevent HIV can work with their healthcare provider to determine the schedule of medical appointments that best meets their needs. Here is a general description of the schedule of medical appointments for PrEP.

- **Initial Medical Appointment:** This first appointment includes education about PrEP, a discussion about readiness to take PrEP, a review of daily versus on-demand PrEP, HIV testing, and other lab work. If the person is ready to start PrEP, the medication can be started right after the initial medical appointment.
- **First Follow-Up Contact:** The healthcare provider and person should make a plan for a follow-up appointment or call at a convenient time, usually within 2-4 weeks, to:
 - Check in on how things are going, including side effects;
 - Troubleshoot any problems with payment or access to support services.

- **HIV testing:** The person should have an HIV test every three months to make sure they have not acquired HIV. The healthcare provider can order the testing which can be done at their office, a conveniently located CBO, health facility or lab. It is important that the results of the test are provided to the healthcare provider who prescribed PrEP.
- **Follow-Up Appointments and Prescription Refills:** The frequency of follow-up appointment is established jointly by the healthcare provider and the person.

5. When I first start taking the medication, how many days do I have to take the medication in order for it to protect me from an HIV exposure?

The PrEP medication must reach and maintain a certain level in the blood and the body's mucus membranes to provide protection. The amount of time it takes may vary from person to person. For people taking daily PrEP who engage in anal intercourse, the medication must be taken each day for 7 days to reach the level needed for full protection. Cis-gender MSM who are taking on-demand PrEP, must take two pills, 2-24 hours before having sex. For the receptive partner in vaginal intercourse, it takes approximately 20 days of taking the medication consistently to reach the level of full protection in the female genital tract. This is why cis-gender women and transgender men who have receptive vaginal intercourse should not take on-demand PrEP. People of transgender experience should talk with their healthcare provider about their specific sexual practices to best determine the length of time it will take to be fully protected.

6. How well does PrEP work?

The PrEP medication works very well at preventing a person from getting HIV. Everyone taking PrEP should be sure to take the medication as agreed upon with the healthcare provider, but it is especially important for cis-gender women and transgender men who engage in vaginal intercourse to take it consistently each day to be fully protected during receptive vaginal intercourse. The more days a person misses a dose, the less protective the medication will be for any exposures that occur during that time period. If you are interested in more specific data regarding how well PrEP works, below is a list of links to the major clinical trials.

- iPrEX: Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team
<https://www.nejm.org/doi/full/10.1056/NEJMoa1011205>
- Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS*. 2016;30(12):1973-1983.
<https://www.ncbi.nlm.nih.gov/pubmed/27149090/>
- Chou R, Evans C, Hoverman A, et al. Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force: Evidence Synthesis No. 178. Rockville, MD: Agency for Healthcare Research and Quality; 2018. AHRQ publication 18-05247-EF-1. <https://www.ncbi.nlm.nih.gov/pubmed/27149090/>

- Molina JM, Capitant C, Spire B, et al; ANRS IPERGAY Study Group. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med*. 2015;373(23):2237-2246. <https://www.nejm.org/doi/full/10.1056/NEJMoa1506273>
- Grant RM, Mannheimer S, Hughes JP, et al. Daily and nondaily oral preexposure prophylaxis in men and transgender women who have sex with men: the Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT study. *Clin Infect Dis*. 2018;66(11):1712-1721. <https://www.ncbi.nlm.nih.gov/pubmed/29420695>
- USPSTF Recommendation Statement on Preexposure Prophylaxis: <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

7. How would I know if PrEP is right for me?

PrEP is one of many options for preventing HIV. HIV is passed from one person to another through sharing injection drug equipment or through anal or vaginal sexual intercourse. People can avoid getting HIV by: 1) not sharing drug injection equipment (needle, syringe, cooker, cotton, etc.), 2) avoiding anal or vaginal intercourse; 3) having only one monogamous sex partner whose HIV status is known to be negative; 4) having only one partner who is living with HIV and has an undetectable viral load. It is important to be aware that a person living with HIV who is on HIV treatment and is virally suppressed for six months or longer cannot pass HIV to a partner through sex. If you have sex with more than one partner, taking PrEP or consistent and correct use of condoms each time you have sex, can prevent you from getting HIV.

New York HIV State Clinical Guidelines indicate that healthcare providers should discuss PrEP as an HIV/STD prevention option for adults or adolescents who:

- Have unprotected anal or vaginal intercourse with: 1) a partner whose HIV status is unknown; 2) a partner who is living with HIV but not on HIV treatment; or 3) a partner who is living with HIV but does not have an undetectable viral load;
- Have unprotected anal or vaginal intercourse with a partner who is living with HIV, on treatment and virally suppressed but wishes to be on PrEP for additional protection;
- Are attempting to conceive with a partner who is living with HIV;
- Have multiple or anonymous sex partners or, have partners who have multiple or anonymous sex partners;
- Participate in sex parties or have partners who do this;
- Are involved in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients, or have partners who do this;
- Have been diagnosed with at least one STI in the previous 12 months;
- Use of mood-altering substances during sex, such as alcohol, methamphetamine, cocaine, and ecstasy;
- Inject substances, or have partners who inject substances, including illicit drugs and hormones;

- Are receiving post-exposure prophylaxis (PEP) and have ongoing high-risk behavior or have used multiple courses of PEP.
- Request the protection of PrEP even if their sex partners have an undetectable HIV viral load (see the discussion of U=U, below).
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of, or anticipates risk behaviors in the near future.

It is important to weigh the pros and cons and have an open and honest conversation about PrEP with your healthcare provider before beginning PrEP. PrEP is always voluntary and only you can determine if PrEP is right for you.

8. Can adolescents consent to PrEP on their own? Does a healthcare provider need the consent of a parent or guardian in order to prescribe PrEP to an adolescent?

2017 amendments to NYSDOH regulations allow minors to consent to their own HIV treatment and HIV preventive services, such as PrEP and PEP, without parental/guardian involvement (10 NYCRR Part 23). The FDA has approved the use of Truvada for adolescents regardless of gender, and Descovy for adolescent cis-gender males. These developments, along with updated [New York State Clinical Guidelines](#), mean that adolescents who are at risk for HIV may consent to PrEP without the involvement of the young person’s parent or guardian.

9. I prefer sex without a condom so I don’t always use them. Would PrEP still work to prevent HIV if I don’t use condoms?

If a person takes the PrEP medication consistently as directed, it provides a high level of protection against HIV. Condoms provide protection against sexually transmitted infections (STIs). People who are on the PrEP medication but are not using condoms may be exposed to an STI. It is important to be aware that having an STI can increase a person’s chance of getting HIV if exposed to the virus. Some STIs don’t have symptoms or symptoms may disappear on their own for periods of time. If you are not using condoms regularly, it would be especially important to have regular testing for STIs and to get treated as soon as possible if you have an STI. Screening for chlamydia and gonorrhea should include swabs of a person’s genitals, rectum and mouth. Learning about the signs and symptoms of STIs is helpful in identifying whether you or one of your partners has an STI. Condom use is recommended but choosing to not use condoms routinely should not prevent you from being prescribed PrEP.

10. I have sex partners who are living with HIV and have an undetectable viral load because they are on HIV treatment. Do I still need to take PrEP?

Individuals living with HIV who are taking HIV treatment consistently and have an undetectable viral load for at least 6 months cannot transmit the virus to an HIV-negative partner through

sexual activity. In sero-discordant or magnetic couples (one person is living with HIV and the other not living with HIV), PrEP may be used by the HIV-negative partner for additional protection.

11. How would I pay for PrEP?

Medicaid will cover the cost of PrEP without co-pays. This includes the medication, medical appointments and lab tests associated with PrEP. Many health insurance plans with prescription drug coverage also cover all costs associated with PrEP without co-pays. For people without access to health insurance with prescription drug coverage, a number of options for financial assistance are available. If you need information about financial assistance options for PrEP, visit the NYSDOH website at:

https://www.health.ny.gov/diseases/aids/general/prep/docs/prep_payment_options.pdf.

12. Can I get the PrEP medication from my regular healthcare provider or do I have to go to a special doctor?

It depends on your doctor. Any physician, nurse practitioner or physician assistant can prescribe PrEP. It is important to have a healthcare provider who you can work with to individualize PrEP to your needs and circumstances. The New York State Department of Health has prepared a directory of healthcare providers that prescribe PrEP that can be found at:

https://www.health.ny.gov/diseases/aids/general/prep/prep_index.htm

13. What are the side effects of the PrEP medications?

Truvada and Descovy are both recognized as well-tolerated medications with few side effects. In clinical trials, only a small number of people found the side effects serious enough to stop taking the medication. People taking PrEP should discuss any side effects they experience with their healthcare provider. In many cases, side effects are only short term and can be managed. Two important health issues related to taking PrEP include kidney function and bone density. Your healthcare provider will ask if you have a history of kidney disease and will periodically order lab work to monitor your kidney function. Bone density will be monitored as needed. The NYSDOH is aware that there are [lawsuits](#) that claim harm to individuals taking Truvada. However, scientific evidence shows that when taken as directed, Truvada is safe and effective. Since there are risks to taking any medication, individuals should speak with their healthcare provider about the benefits, risks (side effects), and possible alternatives for every medication they choose to take in order to understand the best choices for their specific situation.

14. Would I have to take PrEP for the rest of my life? What if I want to stop?

PrEP is not intended to be a life-long program. Rather, it is a program where the healthcare

provider works with you to develop an individualized plan with as many renewals of the prescription as you and the healthcare provider agree to. For many people, life circumstances change over time and the risk for HIV may be reduced or eliminated. You should discuss the issue of how long you want to take the PrEP medication with your provider. If for any reason you want to stop taking the PrEP medication, consult with the healthcare provider who prescribed it, or another provider who is familiar with PrEP. Generally speaking, cis-gender men taking on-demand PrEP should continue taking the PrEP medication for at least 2 days after any possible exposure. Anyone taking daily PrEP should continue taking the medication for 28 days after the last possible exposure.

15. If I drink alcohol and/or use recreational drugs, is it safe to take PrEP?

Alcohol and recreational drugs are not known to interact with PrEP medications. It is safe to take PrEP before, after and on days when you are “partying.” In fact, it is important to take extra steps to make sure you take PrEP according to the healthcare provider’s directions when you are “partying.”

16. Is the PrEP medication effective for treating HIV infection?

PrEP medications are not effective alone for treating HIV infection. If you acquire HIV infection while taking PrEP, the provider who conducted the HIV test should either provide HIV medical care or refer you to a healthcare provider who can provide HIV care. The HIV care provider will conduct lab tests and determine the most effective regimen to treat your HIV infection. There is no evidence that having taken PrEP will impact the effectiveness of your HIV treatment. People who acquire HIV while on PrEP can be successfully treated with HIV medications.

17. Since PrEP medication alone is not effective at treating HIV, is it possible that taking PrEP could lead to my developing drug resistant HIV if I become infected? Could it lead to higher levels of drug resistant virus in the community?

HIV testing is a critical component when using PrEP for HIV prevention. HIV testing is done before a person begins PrEP to ensure that only HIV negative people are prescribed PrEP. Periodic HIV testing for everyone taking PrEP ensures that anyone who gets HIV will be identified quickly so they can be put on an effective treatment regimen. If a person on PrEP gets HIV, drug resistance testing is done to determine an effective treatment regimen. There is no evidence that PrEP can lead to higher rates of drug resistant virus in the community.

**Need Help Paying
for PrEP?**

Pre-exposure prophylaxis is a daily pill that people take so they can reduce their worry about getting HIV.

You may want to consider PrEP if you are:

- A gay or bisexual man who has unprotected anal intercourse
- A transgender woman who has sex with men
- In a relationship with an HIV-positive partner
- Someone who has condomless sex with multiple partners

The six point PrEP program for people who are HIV-negative includes the following:

- Routine HIV testing
- Taking one Truvada pill, once a day, every day
- Using condoms to prevent STDs
- Periodic STD screening
- Education about how to reduce the risk of getting HIV and STDs
- Counseling and support for taking the medication regularly

The New York State Department of Health **Pre-exposure Prophylaxis Assistance Program (PrEP-AP)** will pay for medical appointments and lab services for PrEP if you are uninsured or underinsured. However, you must receive the services from an enrolled PrEP-AP provider.

The PrEP-AP Program does not pay for the cost of the medication. PrEP-AP Enrolled Health Care Providers are required to help patients apply to the drug manufacturer's patient assistance program to cover the cost of the medication.

PrEP-AP will cover the following services including, but not limited to:

- HIV testing
- Adherence counseling and clinical monitoring
- STD testing
- Supportive care services consistent with New York State's HIV Clinical Guidelines

Remember, the provider must be enrolled with PrEP-AP in order for services to be covered.

How do I Enroll in PrEP-AP?

- If you are uninsured or under-insured, you can apply to PrEP-AP using the same enrollment forms as the HIV Uninsured Care Programs/ADAP, which can be found at www.health.ny.gov/diseases/aids/resources/adap/index.htm.
- Enrolled providers can submit claims for all covered services to the PrEP-AP program.
- A PrEP-AP hotline is available to help you with the enrollment process and assistance in accessing comprehensive health care coverage. Call 1-800-542-2437.

Resources

New York State Department of Health PrEP:

www.health.ny.gov/diseases/aids/general/prep/

NYS PrEP Provider Directory:

www.health.ny.gov/diseases/aids/general/prep/provider_directory.htm

HIV Prevention Just Got Easier: www.prepforsex.org

New York State HIV Hotlines: 1-800-541-AIDS or 1-800-233-7432 (Spanish)

New York City Department of Health and Mental Hygiene PrEP:

www.nyc.gov/html/doh/html/living/prep-pep.shtml

Centers for Disease Control and Prevention

www.cdc.gov/hiv/prevention/research/prep/



**Department
of Health**

Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP)

Minor Consent

Amendments to New York’s health regulations allow minors to consent to their own HIV treatment and HIV preventive services such as pre-exposure prophylaxis(PrEP) and post-exposure prophylaxis (PEP) without parental/guardian involvement (10 NYCRR Part 23)

Health Coverage and New York State Department of Health Sponsored Programs	
<p>N.Y. Insurance Law §§ 3216(i)(17)(E), 3221(l)(8)(E) and (F), and 4303(j)(3)</p>	<p>Effective January 1, 2020 all issuers, except for grandfathered health plans, must provide coverage for PrEP for the prevention of HIV infection at no cost-sharing and cover screening for HIV infection at no cost-sharing. See the NYS Department of Financial Services Circular Letter for more information.</p> <p><u>Note:</u> This law does not apply to self-funded plans, wherein an employer is liable for paying all claims for its employees, as Federal law preempts states from regulating these plans. Please consult with an insurance plan representative to determine if cost-sharing applies.</p>
<p>Commercial Insurance</p>	<ul style="list-style-type: none"> • Most commercial insurance plans cover PrEP for adults and adolescents. • Coverage varies based on plan. There may be deductibles and co-payments. • Adolescents may ask that the EOB be sent to another address, but parents may still receive financial information such as co-payments made. This is permitted under Insurance Law 2612(h)(2)(A) and Title 11 of NYCRR, section 23.4 • Co-pay coupons are available through the manufacturer regardless of income. Gilead: 1-877-505-6986
<p>Fee-for-Service Medicaid</p> <p>Helpline: 1-800-541-2831</p>	<ul style="list-style-type: none"> • Medicaid covers PrEP for adults and adolescents, including PrEP prescription costs, medical appointments, and lab tests. • Medicaid does not issue EOBs. Adolescent confidentiality is protected. • Initial fill does not require pre-authorization. For subsequent fills the patient must have an HIV negative test documented within the last 90 days.
<p>Medicaid Managed Care</p>	<ul style="list-style-type: none"> • Medicaid Managed Care Plans (MMCPs) cover PrEP for adults and adolescents. • Prior authorization requirements may vary among plans. • MMCPs are required to send notice upon a service or claim denial, where the denial was not based on medical necessity, the enrollee already received the service, and the enrollee is not liable for the cost of the service, consistent with the Department of Health’s Policy for the Protection of Confidential Health Information for Minors Enrolled in NYS Medicaid Managed Care Plans. • An adolescent may work with their plan or provider to obtain consent to send notices to an alternate address.

Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP)

<p>PrEP Assistance Program (PrEP-AP)</p> <p>Hotline: 1-800-542-2437</p>	<ul style="list-style-type: none"> • PrEP-AP serves adults and adolescents who are residents of New York State and are uninsured or underinsured and prescribed PrEP. • Financial eligibility is based on 500% of the Federal Poverty Level (FPL). • Covers costs of clinical visits and lab testing for uninsured and underinsured individuals. Services include HIV, STI/STD testing, counseling, and supportive primary care services consistent with clinical guidelines for PrEP. • PrEP medication is not covered by PrEP-AP. Manufacturer’s patient assistance programs (PAP) (listed below) should be contacted for uninsured or underinsured individuals. • Providers that are enrolled in the New York State Medicaid Program are eligible to enroll in PrEP-AP. To become a PrEP-AP provider contact the ADAP Provider Relations Section at 1-518-459-1641 or email damarys.feliciano@health.ny.gov for more information. • Providers are responsible for assisting patients with the patient assistance program application to receive their PrEP medication.
<p>Medication Assistance Programs</p>	
<p>New York City</p>	<p>In New York City, there are other options available for low cost access to PrEP. Visit the NYC Health Map. Select “Sexual Health Services” from the services menu. Then select “PrEP and PEP” and “Sliding Scale for Uninsured” under “Cost” to find locations offering this service.</p>
<p>New York State</p>	<p>NYSDOH-funded Adolescent/Young Adult Specialized Care Center providers can provide information and assistance navigating PrEP services and payment options for adolescents and young adults 13 - 24 years old. Contact amcare@health.ny.gov to find the nearest provider.</p>
<p>U.S. Department of Health and Human Services – “Ready, Set, PrEP”</p> <p>855-447-8410</p>	<p>“Ready, Set, PrEP”, is a national program that makes PrEP medications available at no cost to people without prescription drug insurance coverage. GetYourPrEP.com or 855-447-8410. (9:00am – 8:00pm EST Monday – Friday)</p> <p>To qualify, patients must:</p> <ul style="list-style-type: none"> • lack prescription drug coverage, • be tested for HIV with a negative result, • have a prescription for PrEP, and • have no current or prior enrollment in the Gilead Advancing Access Patient Assistant Program within the previous 12 months. <p>There is no income eligibility requirement for this program.</p>
<p>Gilead Co-Pay Coupon Program</p> <p>1-877-505-6986</p>	<ul style="list-style-type: none"> • Covers up to \$7,200 per year in prescription co-payments for Truvada and Descovy. • Patient must have commercial insurance. • Patient must NOT be enrolled in Medicare or Medicaid. • No income eligibility requirement. • For individuals under the age of 18 a patient representative will need to attest/sign on the minor’s behalf.

Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP)

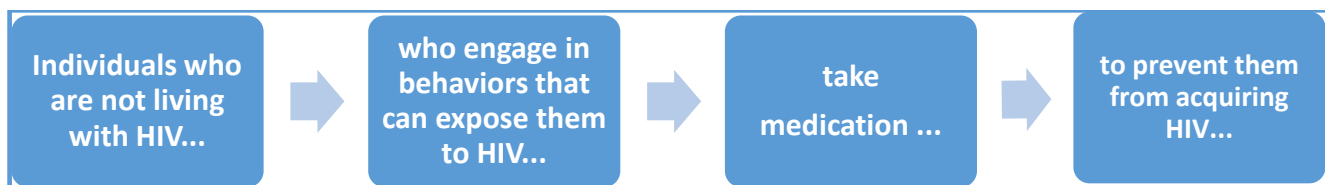
<p><u>Gilead Advancing Access Patient Assistance Program</u></p> <p>1-800-226-2056</p>	<ul style="list-style-type: none"> Covers prescription costs for Truvada and Descovy. Patient must be uninsured or their insurance does not cover any prescription cost. Patient must have annual income less than 500% of the FPL based on household size. For individuals under the age of 18 a patient representative will need to attest/sign on the minor's behalf.
<p><u>Patient Advocate Foundation Co-Pay Relief Program</u></p> <p>1-866-512-3861</p>	<ul style="list-style-type: none"> Provides financial assistance to financially and medically qualified patients for co-payments, co-insurance, and deductibles. Offers grant of up to \$7,500 per year. Patients, their medical providers, or their pharmacists may submit applications 24 hours a day online or via phone Monday - Friday 8:30am – 5:30pm EST. Patient must be currently insured and have coverage for the medication. Patient must have annual income less than 400% FPL. Individuals under the age of 18 years may participate with parental/guardian consent.
<p>Helpful Resources</p>	
<p><u>Partnership for Prescription Assistance Program</u></p> <p>1-888-477-2669</p>	<ul style="list-style-type: none"> Online resource that helps uninsured and underinsured patients find programs that provide prescription medicines at low or no cost. Complete a brief questionnaire with basic information including prescription medicines, age, income and current prescription coverage (if any). PPA searches its database for prescription assistance programs that might be able to help and displays the results.
<p><u>Gilead Advancing Access</u></p> <p>1-800-226-2056</p>	<ul style="list-style-type: none"> Helps guide patients through the process of understanding the type of insurance they have and alternative coverage if needed. Can help match patients to a program that best meets their financial needs based on their circumstances, insurance situation and the eligibility criteria for the programs.

What Support Services Providers Should Know About HIV Clinical Guidelines: Improving Health Outcomes Series

New York State Department of Health AIDS Institute

TOPIC: PrEP to Prevent HIV and Promote Sexual Health

WHAT IS PrEP?



BACKGROUND

Pre-exposure prophylaxis (PrEP) is a commonly used biomedical approach for promoting wellness and preventing an unwanted health outcome. In PrEP for HIV, a person who is not living with HIV takes antiretroviral medication to protect them from a possible exposure to HIV. Clinical trials have consistently found PrEP for HIV to be safe and effective for adults and adolescents when taken as prescribed. Expanding access to PrEP is one of the three pillars in New York's plan to end the AIDS Epidemic. Support services providers who serve people living in situations that place them at risk for HIV have an important role to play in promoting PrEP.

Common Examples of Pre-Exposure Prophylaxis

It may seem unusual to give medication to a healthy person, but here are some common examples:

1. A woman taking birth control pills to prevent pregnancy;
2. A traveler taking anti-malaria medications when going to an area where there is high likelihood of exposure to malaria;
3. A person taking antibiotics prior to dental surgery to prevent infection.

THE ROLE OF SUPPORT SERVICES PROVIDERS IN PROMOTING PrEP

Support services providers can play an important role in promoting appropriate use of PrEP by:

1. Presenting PrEP as a proactive way for adults and adolescents to promote their sexual health and referring people who can benefit from PrEP to a healthcare provider that prescribes PrEP;
2. Working as part of a team to provide clients who are taking PrEP with condoms, harm reduction support, HIV testing, STI screening, and referrals for other needed support services;
3. Supporting treatment adherence for people on PrEP by reinforcing the importance of taking the medication as prescribed by the healthcare provider;
4. Educating clients that PrEP does not offer protection against other STIs and reinforcing the importance of condom use;
5. Helping clients on PrEP who receive a confirmed positive HIV test result to immediately access healthcare and begin an effective HIV treatment regimen;
6. Educating clients about the cost of PrEP and navigating financial assistance programs.

Who can benefit from PrEP?

New York State HIV Clinical Guidelines indicate that medical providers should discuss PrEP as an HIV/STD prevention option for adults or adolescents who:

- Have unprotected anal or vaginal intercourse with: 1) a partner whose HIV status is unknown; 2) a partner who is living with HIV but not on HIV treatment; or 3) a partner who is living with HIV but not virally suppressed (i.e. does not have an undetectable viral load);
- Have unprotected anal or vaginal intercourse with a partner who is living with HIV, on treatment and virally suppressed but wishes to be on PrEP for additional protection;
- Are attempting to conceive with a partner who is living with HIV;
- Have multiple or anonymous sex partners or, have partners who have multiple or anonymous sex partner;
- Participate in sex parties or have partners who do this;
- Are involved in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients, or have partners who do this;
- Have been diagnosed with at least one STI in the previous 12 months;
- Use of mood-altering substances during sex, such as alcohol, methamphetamine, cocaine, and ecstasy;
- Inject substances, or have partners who inject substances, including illicit drugs and hormones;
- Are receiving post-exposure prophylaxis (PEP) and have ongoing high-risk behavior or have used multiple courses of PEP;
- Self-identify as being at risk without disclosing specific risk behaviors;
- Acknowledge the possibility of, or, anticipates risk behaviors in the near future.

PrEP TO PROMOTE SEXUAL HEALTH: Sexual pleasure is an important part of a person's overall sense of wellness. PrEP is a proactive way for a person to take charge of their sexual health. PrEP can enhance sexual pleasure by reducing worry about HIV, facilitating regular screening for STIs, and connecting people to a healthcare provider who supports their sexual health and pleasure. Support services providers have an important role to play educating their clients and communities about sexual health and promoting PrEP as a positive way of supporting their own health, the health of their partners, and the health of their larger social networks.

INDIVIDUALIZING PrEP: NYS Clinical Guidelines outline PrEP as a flexible approach to promoting sexual health and preventing HIV. The following elements of PrEP can be negotiated between the individual and the healthcare provider, with ongoing assistance from support services providers, as needed:

1. Same Day Start: In most instances, individuals should be able to begin taking PrEP on the same day as their first appointment with the health care provider for PrEP. HIV testing should be conducted as part of the first visit. Individuals may begin taking PrEP while the results of the HIV test are pending. In cases where the result indicates that the person is living with HIV and the individual has already started PrEP, the healthcare provider should deliver the result and begin the person on an effective HIV treatment regimen as soon as possible, preferably on the same day that the diagnosis is available.

2. **Flexible Schedule of Medical Appointments:** Healthcare providers should work with each person to determine how often medical appointments are needed to manage PrEP. For some people, appointments may be every three months, but others may need only one or two appointments with the healthcare provider per year. People who need additional support with harm reduction or treatment adherence can access it from a conveniently located support services provider.
3. **Screening for HIV/STIs and Other Bloodwork:** Individuals taking PrEP can work with their healthcare provider to make a plan for HIV/STI testing and other bloodwork. In some cases, the person may return to the healthcare providers office for testing but in others, it may be most convenient to have the testing done at a nearby lab, community-based organization or other facility. STI screening can sometimes be done by having a person do their own specimen collection via self-swabbing of the mouth, vagina or anus. Arrangements should be made to ensure that the results are forwarded to the healthcare provider.
4. **Medication and Dosing Options:** Men who have sex with men (MSM) may work with their healthcare provider to choose from two different PrEP medications, Truvada or Descovy. MSM also have the option of daily PrEP or on-demand PrEP.

	Daily PrEP	On-Demand PrEP
Who is it for?	People of all genders who have risk for HIV from sex or sharing injection equipment.	Only for MSM who have predictable periods of sexual risk for HIV and are able to begin taking medication 2-24 hours before having sex.
How does it work?	The person takes one pill every day.	<ol style="list-style-type: none"> 1. An MSM takes 2 pills, 2-24 hours before having sex. 2. An MSM continues to take one pill each day they have sex. 3. An MSM takes one pill once a day for two days after the last time they have sex.
What are the benefits of each method?	<ol style="list-style-type: none"> 1. Works for people of all genders. 2. A person has a simple daily habit of taking the medication. 3. Provides consistent protection. 4. Able to engage in sex or sharing injection equipment at any time with full protection. 	<ol style="list-style-type: none"> 1. MSM can take the medication only for the period of time when it is needed. 2. Possible fewer side effects.

HELP A PERSON FIND A PrEP PROVIDER: Use the NYSDOH voluntary [Provider Directory](#).

ASSISTANCE WITH PAYING FOR PrEP: Medicaid covers the costs associated with PrEP with no co-pays. Some health plans offering prescription drug coverage cover PrEP with no co-pays. Financial assistance is available for people who are uninsured, underinsured or who have significant co-pays for the medication, lab work or appointments. To learn about financial assistance, click on [this link](#).

For the full *PrEP to Prevent HIV and Promote Sexual Health* clinical guidelines visit: <https://www.hivguidelines.org/prep-for-prevention/>.