



Getting PrEP to the patients who need it

A fraction of those eligible for PrEP to prevent HIV infection receive a prescription. Newer drug regimens and updated recommendations can help you reduce that gap.

Andrew V.A. Foley, MD, MPH; Daniel F. Farrell, MD, AAHIVS; Patricia Carr Reese, MD, MPH, AAHIVS
Erie Family Health Centers (Dr. Foley); Hudson Headwaters Health Network (Dr. Farrell); Lancaster General Hospital Physicians Comprehensive Care, Penn Medicine, Lancaster General Health (Dr. Carr Reese)

andrewvafoley@gmail.com

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PRACTICE RECOMMENDATIONS

▶ Perform routine screening of patients for preexposure prophylaxis (PrEP) eligibility. **(B)**

▶ Prescribe oral or intramuscular PrEP for eligible patients after screening for HIV, other sexually transmitted infections, and hepatitis B, and establishing baseline renal function. **(A)**

Strength of recommendation (SOR)

- (A)** Good-quality patient-oriented evidence
- (B)** Inconsistent or limited-quality patient-oriented evidence
- (C)** Consensus, usual practice, opinion, disease-oriented evidence, case series

More than 1.2 million Americans are living with HIV, and more than 30,000 new cases are diagnosed each year. While total incidence has declined since 2016, HIV remains a nationwide epidemic.¹

Medications that prevent HIV acquisition, termed *pre-exposure prophylaxis* (PrEP), are an important tool to initiate in the primary care setting to reduce HIV transmission. However, while there are an estimated 1.2 million people eligible for PrEP, only 36% have received PrEP prescriptions.² Several barriers that have impeded its widespread adoption include a lack of clinician knowledge and clinical resources for testing, high medication costs, and stigma around sexual health and intravenous (IV) drug use.

The value of PrEP

PrEP is chemoprophylaxis against the acquisition of HIV infection through the administration of an oral or injectable medication to people at risk for HIV. This practice began in the early 2000s, with the first oral regimen approved in 2012, and since has become an important tool in preventing HIV transmission.

When taken as prescribed, PrEP medications reduce the risk for acquiring HIV through sex by approximately 99% and can reduce the risk for acquiring HIV from injection drug use by approximately 74%.³ The US Preventive Services Task Force issued a Grade “A” recommendation to offer PrEP to people at high risk for HIV acquisition in June 2019 and reaffirmed it in a 2023 update.⁴

PrEP is notably distinct from postexposure prophylaxis (PEP), which is the administration of medication to prevent HIV infection after a possible exposure.

The available regimens

Regimens for PrEP include oral tablets or intramuscular

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Incomplete adherence to or abrupt discontinuation of oral PrEP could precipitate a hepatitis B flare.

(IM) injections.⁵ There are 3 PrEP regimens approved by the US Food and Drug Administration (FDA): tenofovir disoproxil fumarate/emtricitabine (Truvada), tenofovir alafenamide/emtricitabine (Descovy), and cabotegravir (Apretude).

■ **Truvada** is once-daily oral PrEP that was approved in 2012 and is now available in a generic formulation. Notable adverse effects of Truvada include a small negative impact on renal function and small reductions in bone mineral density; these have been noted in individual trials, but in meta-analyses such differences were not found to be statistically significant.⁶⁻⁸ The most common adverse effects of Truvada, experienced by up to 6% of patients, are gastrointestinal symptoms, fatigue, headache/dizziness, depression, and insomnia; most symptoms resolve within weeks.

■ **Descovy** is daily oral PrEP that was approved in 2019. Descovy is associated with increases in LDL and triglycerides but has less impact on renal and bone health.⁹ The most common adverse effect of Descovy, experienced by about 5% of patients, is diarrhea, followed by nausea.

■ **Apretude** was approved in 2021 and is a 600-mg IM injection given monthly for 2 months, then every 2 months (\pm 7 days). The advantages of Apretude are frequency and discreteness of dosing and the ability to use in patients with estimated creatinine clearance (eCrCl) > 15 mL/min. The most common adverse effects of Apretude are injection-site reactions, which occur in 30% to 80% of patients but are rarely significant enough to lead to discontinuation (< 2% of patients discontinue use due to injection-site reactions).¹⁰

Who should take PrEP?

The latest Centers for Disease Control and Prevention (CDC) guidelines recommend that all sexually active adults receive information about PrEP.⁵ Indications for PrEP are broad and summarized in the **FIGURE**.⁵

PrEP is indicated in patients who report sexual or injection drug use behaviors that place them at substantial ongoing risk for HIV exposure. Specific indications include patients with sexual partner(s) with unknown

HIV status with whom they have inconsistent or no condom use, a history of bacterial sexually transmitted infection (STI) in the past 6 months, an HIV-positive sexual partner, or the sharing of injection drug equipment.

■ **Hepatitis B infection is not a contraindication for PrEP** use, but knowledge of infection status is essential. All current oral medications used for PrEP have activity against hepatitis B. Incomplete adherence to or abrupt discontinuation of oral PrEP could precipitate a hepatitis B flare. Hepatitis B surface antigen should be tested at the time of PrEP initiation, although PrEP can begin while testing is in process.

How to use PrEP

At PrEP initiation, acute or chronic HIV infection must be excluded with a documented negative HIV antigen/antibody test within 1 week of prescribing PrEP.⁵ The CDC guidelines provide an updated HIV testing algorithm (www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf, p 30-31, Figures 4a and 4b), which considers whether patients have received PrEP recently.

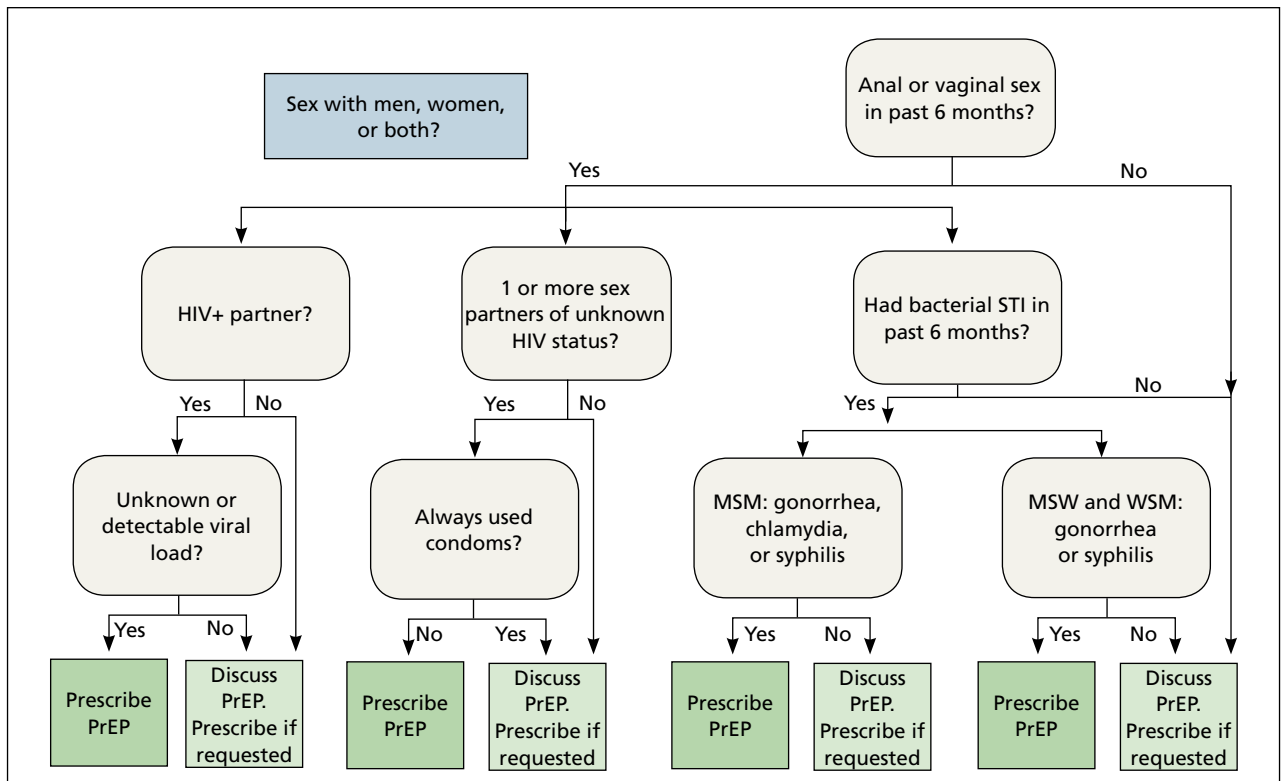
Patients with recent high-risk exposures or symptoms of acute HIV at the time of desired PrEP initiation should have an HIV-1 viral load checked with negative results before PrEP is prescribed. Additional criteria for PrEP include weight > 35 kg; screening for hepatitis B virus infection; screening for drug interactions; and drug-specific eCrCl cutoffs of > 60 mL/min for Truvada, > 30 mL/min for Descovy, and > 15 mL/min for Apretude.⁵

Studies regarding time to medication effectiveness are limited. Pharmacokinetic studies of Truvada demonstrate sufficient drug concentrations should be present in peripheral blood mononuclear cells and rectal tissue within 7 days of initiation of oral dosing and around 20 days in vaginal tissue.

Of note, while expedited partner therapy is used as a harm-reduction strategy to treat the sexual partners of patients diagnosed with certain STIs, PrEP is not recommended to be used in this way.

■ **Ongoing monitoring with PrEP.** Once oral PrEP is started, STI risk assessment and HIV testing via 4th generation antibody/

FIGURE

Assessing indications for PrEP in sexually active people⁵

MSM, men who have sex with men; MSW, men who have sex with women; PrEP, preexposure prophylaxis; STI, sexually transmitted infection; WSM, women who have sex with men.

antigen test should be completed at least every 3 months. PrEP oral prescription refills should be limited to 3 months. For patients receiving IM PrEP (Apretude), HIV testing via viral load and antibody/antigen testing should be done at the time of each injection (every 2 months).⁵

With oral PrEP, renal function should be checked every 6 months in patients older than 50 years or those with eCrCl < 90 mL/min at initiation. For patients younger than 50 years with no baseline renal dysfunction, the latest guidelines now recommend monitoring every 12 months instead of 6 months.⁵

For patients on Descovy, a lipid panel is recommended at PrEP initiation and every 12 months. Testing for other STIs can be considered on this schedule, based on clinical assessment. The TABLE⁵ summarizes recommended monitoring for patients taking oral PrEP.

■ **Recommended follow-up provides an opportunity** to have frequent contact

with a potentially high-risk population, and PrEP should be one part of a comprehensive HIV prevention and risk reduction plan. Many patients at high risk for HIV acquisition may benefit from frequent follow-up to address screening, referral, and treatment of substance use disorders, mental health conditions, and chronic medical conditions (including hepatitis C infection) and provide ongoing preventive health care.

Special uses of PrEP

■ **Same-day PrEP.** Starting PrEP on the day of the initial appointment may be appropriate based on patient risk factors and barriers to care, such as a high risk for contracting HIV before the subsequent appointment for a prescription of PrEP or an inability to return to the clinic in a timely fashion due to transportation or work constraints, or clinician availability. For these patients, assuming there is a low concern for acute or chronic HIV infec-

TABLE

Follow-up and monitoring while on oral PrEP⁵

Test	Screening/ baseline visit	Every 3 mo	Every 6 mo	Every 12 mo	When stopping PrEP
HIV	X ^a	X	NA	NA	X ^a
eCrCl	X	NA	If age ≥ 50 y or eCrCl < 90 mL/min at PrEP initiation	If age < 50 y and eCrCl ≥ 90 mL/min at PrEP initiation	X
Syphilis	X	MSM/TGW only	X	NA	MSM/TGW only
Gonorrhea	X	MSM/TGW only	X	NA	MSM/TGW only
Chlamydia	X	MSM/TGW only	X	NA	MSM/TGW only
Lipid panel ^b	X	NA	NA	X	NA
Hepatitis B serology	X	NA	NA	NA	NA
Hepatitis C serology	MSM, TGW, and PWID only	NA	NA	MSM, TGW, and PWID only	NA

eCrCl, estimated creatinine clearance; MSM, men who have sex with men; NA, not applicable; PrEP, preexposure prophylaxis; PWID, people who inject drugs; TGW, transgender women.

^a Assess for acute HIV infection.

^b For those taking tenofovir alafenamide/emtricitabine.

tion, PrEP can be initiated on the day of the initial visit.⁵

In these cases, point-of-care HIV and creatinine testing with same-day results should be completed. Antigen/antibody fingerstick testing or HIV-1 RNA test are preferred; oral fluid HIV testing should not be used for same-day PrEP due to its lower sensitivity for HIV detection. If same-day testing is unavailable, blood should be drawn at the visit so that HIV and creatinine testing can be completed as soon as possible.

In addition to initial laboratory testing, clinics offering same-day PrEP should be able to provide: (1) assistance for patients to enroll in health insurance or a medication assistance program (eg, Ready, Set, PrEP) for those ineligible for insurance coverage, (2) rapid follow-up on all laboratory results with reliable patient contact information, and (3) follow-up appointments with clinicians able to prescribe and administer PrEP medications.

■ **Off-label “on-demand” PrEP.** An off-label treatment regimen for men who have sex with men (MSM) is termed “on-demand” PrEP or “2-1-1 PrEP” and is included in the CDC guidelines for consideration by clinicians.⁵ This alternative dosing schedule can be used for individuals who have sex less frequently and in a more planned fashion.

On-demand PrEP requires a patient to take 2 tablets of Truvada 2 to 24 hours before sex, followed by 1 tablet 24 hours and 1 tablet 48 hours after sexual activity. If a sexual act occurs at 48 hours, the patient should extend the daily dose for 48 additional hours, such that PrEP is always used daily for 48 hours after the last sex act.

This method has been studied with Truvada in MSM in Europe and Canada through the IPERGAY and PREVENIR trials and shown to have ≥ 86% efficacy in preventing HIV acquisition.^{11,12} The only US-based study showed lower efficacy; however, based on the currently available data, the International Antiviral Society-USA Panel has recommended it as an alternative regimen.^{13,14}

■ **PrEP via telehealth.** Visits for PrEP initiation and continuation can be completed via telehealth.⁵ Patients then can complete necessary laboratory tests by going to a physical laboratory location or using mailed specimen kits in which they can self-collect urine, oral/rectal swabs, and fingerstick blood samples.

PrEP use in specific populations

Adolescents

Truvada, Descovy, and Apretude all are now approved for use in adolescents weighing

≥ 35 kg. Two important considerations when prescribing to this population are the effects of Truvada on bone health and the unique barriers to access.

In studies of adolescent MSM using Truvada for PrEP, bone mineral density declined, especially among those ages 15 to 19 years.¹⁵ As such, the clinical impact of decreased bone mineral density should be weighed against the risk for HIV acquisition; however, bone mineral density monitoring is not recommended in the current guidelines. CDC guidelines suggest considering Descovy for male adolescents given its potential lower impact on bone mineral density.⁵

Confidentiality and legal issues exist when prescribing PrEP to minors. In terms of parental/guardian involvement, clinicians who are prescribing PrEP for patients younger than 18 years should consult the CDC website for guidance on local and state regulations that govern prescribing and confidentiality (www.cdc.gov/hiv/policies/law/states/minors.html).

Insurance billing statements may lead to inadvertent disclosure of a minor's decision to take PrEP to their legal guardian.¹⁶ Generic Truvada costs less than \$100 for a 3-month supply when using goodrx.com, which may offer an alternative to insurance for medication payment.

Peripartum patients

The increased risk for HIV acquisition in the peripartum period for female patients is well documented.¹⁷ Guidelines recommend offering PrEP with Truvada to female patients at risk for conception, currently pregnant, or breastfeeding when that patient's partner has HIV and the partner's viral load is unknown or detectable. Descovy is not recommended for pregnant or breastfeeding patients.⁵ Cabotegravir-containing regimens (Apretude) have not been approved by the FDA for pregnant or breastfeeding patients.⁵

Data on the impact of Truvada for PrEP on fetal health are still emerging. A large study in Kenya showed no significant differences in preterm birth, low birth weight, or early infant growth, and a randomized, noninferiority trial in South Africa showed no association between Truvada for PrEP and preterm

birth or the birth of small-for-gestational-age infants.^{18,19} There are no definitive studies of breastfeeding infants exposed to Truvada, but data from previous trials of breastfeeding mothers who were taking the individual components that are combined in the Truvada pill indicated there is minimal medication exposure to the infant.⁵

PrEP studies in the peripartum period to date have been conducted exclusively among cisgender women, and data do not yet reflect the experiences of transgender men, gender-queer people, and nonbinary individuals in the peripartum period.⁵

Transgender people

Transgender women should be strongly considered candidates for PrEP as they are at an extremely high risk for HIV acquisition. The most recent National HIV Behavioral Surveillance survey found that approximately 42% of transgender women were living with HIV.²⁰ The survey revealed stark racial and ethnic disparities among transgender women living with HIV: 62% identified as Black/African American, compared with 35% Hispanic/Latina and 17% White.²⁰

Transgender women report high rates of sexual assault, unprotected receptive anal sex, commercial sex work, homelessness, mental health disorders, and substance use, putting them at increased risk for HIV acquisition.²¹ However, transgender women are less likely to have discussed PrEP with a clinician, are less likely to be on PrEP even when interested in starting, and have higher rates of medication nonadherence compared with cisgender MSM.^{21,22} PrEP has not been found to decrease levels of feminizing hormones; however, studies are mixed as to whether feminizing hormones decrease Truvada concentrations in rectal mucosa, so clinicians should emphasize the importance of daily medication adherence.²³

Transgender men have not been included in any PrEP trials, so no specific recommendations are available.

Disparities in PrEP access and use exist

The lifetime risk for HIV acquisition is 9%



CDC guidelines suggest considering Descovy for male adolescents given its potential lower impact on bone mineral density.

➤ Rural areas have been shown to lag behind urban areas in PrEP awareness and use.

among White MSM, 50% among Black MSM, and 20% among Hispanic MSM.²⁴ Despite this large disparity in disease burden, Black and Hispanic individuals are less likely to be aware of PrEP, have discussed PrEP with a health care professional, or used PrEP compared with their White counterparts.²⁵ As a result, in 2020, PrEP coverage for eligible White individuals was 61%, while coverage among eligible Black and Hispanic/Latino individuals was just 8% and 14%, respectively.²⁶

Surveillance data comparing male and female PrEP coverage reveal further disparities between the sexes, with PrEP coverage for eligible female-at-birth patients estimated to be 9% compared with 25.8% for male-at-birth patients.²⁶ The gap between the risk for HIV infection and the access to and uptake of PrEP coverage is most pronounced among Black women, for whom the rate of new HIV diagnosis is > 10 times higher than it is for White women, but who have some of the lowest awareness and utilization rates of all demographics.²⁷

■ **The rural population at risk.** Disparities in HIV awareness and PrEP use also exist between rural and urban populations, as well as by health insurance status. Rural areas have been shown to lag behind urban areas in PrEP awareness and use. Two potential explanations for this disparity are differences in HIV- and drug use-associated stigma and health insurance status. Greater stigma against drug use and HIV in rural areas has been associated with lower rates of PrEP use.²⁸

Individuals younger than 65 years in rural areas are less likely to have private health insurance and more likely to be uninsured compared with their urban counterparts, which may impact access to clinicians knowledgeable about PrEP.²⁹ Notably, MSM who live in states that have expanded Medicaid have higher rates of PrEP use compared with MSM living in states that have not expanded Medicaid.³⁰

Health insurers in the United States are required to cover PrEP medication, clinician visits, and associated blood work with no patient cost-sharing, although implementation barriers such as prior authorizations still exist.

Conclusion

Family physicians are well positioned to identify patients at risk for HIV infection, prescribe PrEP, organize comprehensive follow-up care, and partner with their health systems and local communities to reduce barriers to care. Those who can leverage existing relationships with local health departments, school-based health clinics, congregate housing programs, LGBTQIA+ advocacy groups, harm-reduction coalitions, and other community-based organizations to raise PrEP awareness play a critical role in preventing HIV transmission and reducing health care disparities in their communities. **JFP**

CORRESPONDENCE

Andrew V.A. Foley, MD, MPH, Erie Family Health Centers, 2418 W Division Street, Chicago, IL 60622; andrewvafoley@gmail.com

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