



# Is PrEP Appropriate for Urgent Care?

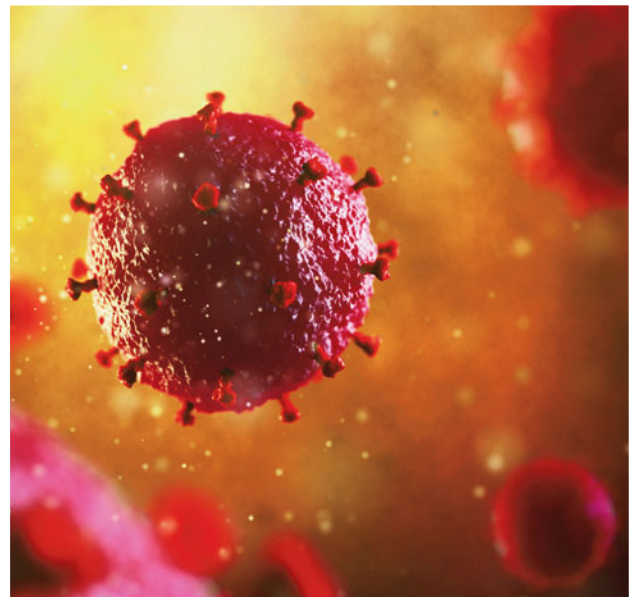
**Urgent message:** Ever since HIV pre-exposure prophylaxis (PrEP) was approved by the FDA in 2012, urgent care centers have been offering this service in increasing numbers as a way to increase revenue and serve new patient segments. However, some healthcare professionals question whether urgent care is an appropriate venue for dispensing such a powerful medication, as it can carry with it dangerous side effects and, if misused, serious health consequences.

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Although healthcare statisticians haven't tallied the precise numbers, the data clearly point to patient populations most at risk for contracting a sexually transmitted disease or infection (STD/I) as being those least likely to have a primary care doctor. This has led many of these patients to the doors of urgent care centers for treatment, and over the years has established urgent care as a convenient and capable provider of diagnosis, testing, treatment, risk assessment, and counseling for a broad range of common STD/Is. Look no further than the fact that urgent care as a whole has seen a threefold increase between 2010 and 2014 in requests for services related to STD/Is, with the numbers undoubtedly growing since then.<sup>1</sup>

This increase in utilization for STD/Is combined with the landmark 2012 FDA approval of HIV-prevention drug Truvada, manufactured by Gilead, has paved the way for urgent care centers to expand their sexual health service offerings beyond typical STD/I treatment, and into a growing, high-demand subspecialty: pre-exposure prophylaxis (PrEP).

Indeed, the larger healthcare community sees urgent care as an increasingly viable option for providing PrEP services to at-risk patient groups, so long as it doesn't become a proxy or replacement for comprehensive primary care HIV prevention. And as PrEP is widely endorsed by organizations such as the World Health Organization (WHO), Centers for Disease Control and Prevention, and the HIV.org National HIV /AIDS Strategy, awareness, understanding, and the willingness to prescribe it has increased among urgent care providers.



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However, there exists a segment of the urgent care community that has expressed strong ethical reservations against widespread PrEP dispensing in urgent care—mostly surrounding issues of the medication encouraging “risk compensation” among patients, and the health consequences of nonadherence to strict dosing regimens.

With those factors in mind, here we provide a basic overview of PrEP, and answer essential questions the urgent care operator must consider when thinking about providing PrEP services.

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**What is PrEP?**

HIV pre-exposure prophylaxis, or PrEP, is a medication taken in pill form (brand name Truvada) once a day, by mouth, with or without food. Approved by the FDA in July of 2012, PrEP consists of two anti-retroviral medicines: tenofovir and emtricitabine. A PrEP regimen is recommended for people who do not currently have HIV but who engage in behaviors that heighten their risk for exposure to the virus. So in effect, PrEP is a preventative treatment to be administered before infection occurs.

PrEP stops HIV from reproducing and establishing an infection in the body by blocking a key enzyme necessary for virus replication. The medicine requires 7 to 20 days to take full effect in the patient's system. PrEP loses its effectiveness if doses are skipped, or there is inconsistent adherence to the prescribed dosing regimen. The pill can be safely discontinued at any time if the patient experiences an adverse reaction to the drug, experiences serious side effects, or if the patient's activities and behaviors result in a decrease in their HIV infection risk levels. When the dosing regimen is strictly adhered to, PrEP is 99% effective in preventing HIV infection.<sup>2</sup>

**How PrEP Differs from PEP and TasP**

PrEP differs from postexposure prophylaxis (PEP)<sup>3</sup> in that while PrEP is intended to prevent an HIV infection from ever developing, PEP is an antiretroviral therapy taken by a non-PrEP user after a single high-risk HIV exposure event (such as a needle-stick injury) where a new infection is suspected to be in the process of seroconversion. Although it is recommended that PEP be initiated within 72 hours of the high-risk exposure event, experts have observed that the therapy can in some cases remain effective beyond the 72-hour initial exposure window.<sup>3</sup>

*Pre-exposure prophylaxis (PrEP) differs from postexposure prophylaxis (PEP) in that PrEP is prescribed to high-risk populations—those engaged in behaviors likely to contract HIV—to prevent HIV infection. PEP is prescribed after a potential exposure to HIV, which may include workplace scenarios such as a needle-stick injury. While*

*“Though some see this as a way to increase revenue and provide much-needed healthcare services, critics contend that the urgent care model is ill-equipped for safe and effective PrEP dispensing.”*

*PrEP largely applies to personal risks involving sexuality, PEP may be part of an occupational health program benefitting police, fire, EMS, nurses, lab technicians, and others at risk for occasional accidental exposure to HIV contaminated blood.*

PrEP also differs from HIV treatment as prevention (TasP),<sup>4</sup> which refers to a regimen of prevention methods that employ antiretroviral treatment (ART) to decrease the HIV viral load in an already-infected individual's blood, semen, and vaginal or rectal fluid. The aim is to reduce the viral load to such low levels that it's virtually undetectable in blood tests, effectively eliminating the ability to transmit HIV to another person.<sup>4</sup>

**Who is PrEP Prescribed for?**

PrEP is for individuals at the greatest risk of becoming infected with HIV through their sexual practices or drug use. It has been estimated that out of the 1.2 million people in the U.S. considered at the greatest risk for contracting HIV, only 79,000 are currently on a PrEP regimen as of 2016.<sup>5</sup> Further, recent CDC surveillance data show that the age group that produced the highest number of new HIV cases was young adults between the ages of 20 and 34.<sup>5,6</sup>

According to guidelines set forth by the CDC, the following groups of people are considered candidates for PrEP:

- HIV-negative individuals who currently have sex with an HIV-positive partner.
- Bisexual or gay men who are not in a monogamous relationship with a tested, HIV-negative partner, or who have either had condomless anal sex in the last 6 months or contracted an STD/I within the last 6 months.
- Heterosexual individuals (regardless of gender) who are not in a monogamous relationship with a verified HIV-negative partner, or who do not consistently use condoms with partners having unknown HIV status, or who are otherwise at high risk of HIV infection—for example, individuals who have bisexual male partners or inject drugs intravenously.

**Table 1. Guidelines for Urgent Care PrEP Services**

In the January-February 2018 issue of the *Journal of the Association of Nurses in AIDS Care*, clinicians Yeow Chye Ng, PhD, Angela Cairns, DNP, and Jack Mayeux, MSN put forth a practice brief proposing a PrEP implementation guideline based on the lessons they learned prescribing PrEP in an urgent care facility. Although the authors admit that they cannot foresee the long-term ramifications of urgent care PrEP services, they do offer a protocol for urgent operations that have the facilities, clinical resources, and staffing to perform PrEP services, compiled in a series of lessons.<sup>8</sup>

**Lesson 1: Establish a Standard Service Protocol**

The urgent care facility must establish a standard PrEP service protocol that includes a current list of local HIV prevention clinics, primary care providers, and subspecialty providers (eg, substance abuse counselors, mental health, hepatologists, etc.). Additionally, it must be made clear to patients that they will need to follow up with their PCP or local HIV prevention facility for future PrEP maintenance.

**Lesson 2: Know Your Local HIV Providers and Community Clinics**

As HIV prevention requires a multidisciplinary approach, it's important the urgent care familiarize itself with and collaborate with the local HIV prevention and treatment centers in the surrounding community. They should study the current PrEP treatment protocol and integrate it within their own clinical setting wherever feasible. This will provide a standardization for patients, allowing them to seamlessly transition into the longer-term facilities they must go to for ongoing PrEP maintenance. Additionally, urgent care must be prepared to be supportive of patients transitioning to longer-term facilities as HIV stigma is very powerful and there may be initial hesitation.

**Lesson 3: We Support Our Patients' Desire for Care**

Patients who take responsibility for their healthcare and show up at an urgent care center seeking PrEP should be commended and welcomed with open arms. As patients may have had to muster considerable courage to open up and discuss their backgrounds and lifestyle with the provider, they should feel empowered to do so without the risk of judgment. This can be a sensitive and lifesaving encounter; hence, urgent care providers must take the necessary time to listen empathetically and offer the most helpful advice and knowledge possible.

**Lesson 4: We Are Here to Prevent New Cases of HIV**

When dealing with a patient with an active STD/I, don't hesitate to inquire about their sexual behaviors. By listening in confidence, the urgent care not only positions itself as a compassionate provider, but can gain knowledge about local, closed-door, sexual social events taking place in the surrounding community. And out of these discussions may arise the opportunity to get more specific in patient sexual education, helping the patient better understand the risks inherent in certain sexual practices.

**Lesson 5: Know When to Say No**

Don't be afraid to inform a patient when he or she is not a viable candidate for PrEP services. There could any number of issues that disqualify them, such as a medical condition where PrEP is contraindicated or a substance abuse/chemical dependency issue. However, the clinician should provide a referral to a local HIV community resource, and thoroughly document the reasons for denying PrEP during that visit.

**Lesson 6: Oh, By the Way, I Need...**

Inevitably, during a visit there will be patients who seek additional care beyond the PrEP prescription. The medical complaint could be related to sexual health, or it could be something wholly separate. Although the discretion as to what to treat is up to each individual provider, it is strongly advised that the provider treat only the PrEP issue during that visit.

**Lesson 7: Know Your Biller/Coder**

As prescribing PrEP from an urgent care setting is not yet a common occurrence, the billing department may need additional guidance. Therefore, the billing process and the necessary coding language will have to be laid out in detail, to include the lab tests. If additional follow-up with the claims department is required, especially in the beginning of PrEP service implementation, be sure to allocate the necessary time and attention for it.

- Intravenous drug users who have injected drugs, had sex with people who have injected drugs, have shared needles used to inject drugs, or been in a drug treatment program within the last 6 months.
- Sex workers.
- People who are trying to become pregnant with a known HIV-positive partner.
- People who have had a recent STD/I in the anus or vagina.

**Side Effects of PrEP**

Although most people tolerate PrEP very well, there are always a few individuals who will experience adverse side effects when their body interacts with the drug. Symptoms can vary from person to person, and can include the following:

- **Nausea** – Primarily occurs at the beginning of treatment when the body is adjusting to the drug.

Patients can experience feelings of queasiness, stomach discomfort, or the urge to vomit. These symptoms will usually pass after a few weeks and can be lessened when the Truvada tablet is taken with food.

- **Headaches** – Headaches can result from the body adjusting to the drug but should subside after a few weeks. If headaches persist or worsen after a few weeks of initiated PrEP treatment, the patient is directed to consult their physician or healthcare provider.
- **Diarrhea** – Diarrhea and loose stools are also a common side effect of PrEP, especially in the beginning stages of the drug regimen. As with headaches and nausea, the symptoms should lessen or subside after a few weeks, and if they persist, the patient should seek counsel from their healthcare provider.

While the above side effects are considered relatively

minor, there are additional, more serious side effects that can arise from PrEP use, and negatively impact a patient's health over an extended PrEP dosing regimen. These can affect:

- **Liver health** – In rare occurrences, PrEP can negatively impact liver health. If a patient notices the whites of their eyes or their skin take on a yellowish tint, it could indicate that PrEP is causing a problem with their liver function; hence, they should contact their healthcare provider immediately. Dark-colored urine and a loss of appetite could also be symptoms of impaired liver function and should be brought to the attention of the healthcare provider.
- **Kidney health** – Kidney health can also be adversely impacted by PrEP, which is why lab tests ensuring renal health are a primary prerequisite for beginning any PrEP drug regimen. In rare cases, there may be impaired kidney function during the course of PrEP treatment; therefore, a patient experiencing kidney issues should be closely monitored by the healthcare provider.<sup>7</sup>
- **Loss of bone density** – Although rare, PrEP can lead to a loss of bone mineral density, increasing the risk of bone fractures. And while this loss of bone density can be reversed by cessation of PrEP, patients with a history of osteoporosis or other bone diseases should consult their doctor before beginning a new regimen.

### PrEP Treatment in the Urgent Care Setting

Before a patient can begin a new PrEP regimen, their eligibility must be assessed. First, they will be interviewed by a healthcare professional to determine whether they are a candidate for PrEP. This will include a series a question about their prior health history with STD/Is or other relevant medical conditions, infections, or diseases. Additionally, the patient will be asked questions about their sexual activities, preferences, and behaviors.

Next, the patients will be required to partake in a battery of lab tests and other screenings to rule out any conditions

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that would be contraindicated for PrEP. These conditions can include an active STD/I, active HIV infection, renal impairment, or hepatitis B or C. If the patient is determined to be a candidate, the provider will start him/her on a Truvada regimen for a minimum of 30 days, up to 90 days. After 90 days, the patient would be required to return to the provider or another healthcare provider for additional testing should they want their Truvada prescription renewed. Additionally, a broad-ranging educational and prevention strategy will commence in conjunction, and can include the following measures:

- Insurance counseling and/or information on how to obtain free PrEP drugs
- Education on safe sex practices
- Education on the proper and consistent use of condoms
- A regular testing schedule for STD/Is
- Resources for obtaining clean, unused needles
- Health and wellness counseling

**Table 1** provides some basic guidelines for administration of PrEP in the urgent care setting.

### Ethical Reservations and Concerns Regarding PrEP

Though many in the healthcare community hailed the advent of Truvada as a watershed moment in the fight against HIV/AIDS, many others raised serious ethical concerns about the drug. The primary concerns voiced by skeptics and dissents generally fall within two basic categories:

- **Risk compensation** – Concern that the drug would create a false sense of security among high-risk individuals, leading to an increase in risky behavior (along with a concomitant increase in STD/I infection rates)
- **Nonadherence** – Concern that nonadherence to strict dosing regimens could result in the creation of virulent HIV strains that are resistant to Truvada

### Risk Compensation

Many healthcare professionals remain concerned that the widespread availability of a preventative treatment

**Table 2. PrEP Considerations for the Urgent Care Provider**

Although some urgent care centers have already begun offering PrEP services, there is debate as to whether the venue is appropriate for dispensing a medication so fraught with consequences of misuse. As urgent care utilization for STD/I services continues to see yearly increases, however, many see PrEP services as a logical next step. With that in mind, here are a few of the pros and cons of offering PrEP services that the urgent care operator must consider:

Pros	Cons
<ul style="list-style-type: none"> <li>• Offering PrEP positions may help the urgent care center expand its market to include previously underserved patient groups, including the LGBTQ community.</li> <li>• Additional revenue stream (includes cash pay patients) may be realized for the initial consultation, laboratory testing and screening, and ongoing prescription maintenance.</li> <li>• A location that offers PrEP provides a much-needed service to the community in the form of another option for HIV high-risk individuals to seek preventive care.</li> </ul>	<ul style="list-style-type: none"> <li>• Urgent care is focused on servicing episodic conditions and treating patients quickly and efficiently. Thus, a clinical model designed to maximize throughput may be poorly equipped to provide the time-consuming sexual health assessment, counseling, and long-term maintenance necessary in PrEP services.</li> <li>• As urgent care is a draw for patients seeking convenience above all else, the mindset lends itself to a disinterest in the ongoing testing and counseling necessary for a safe and effective PrEP regimen, putting the patient at a high risk of failure.</li> <li>• Many patients seeking PrEP have complicated social, family, and medical histories—including illegal substance abuse, gender hormone use, behavioral health issues, and other infections—that necessitates a mental health provider willing and able to spend the time needed to perform a full psychological profile on the patient.</li> <li>• Patient satisfaction is tied directly to wait times; therefore, expanding into a diversity of time-consuming services increases the complexity of the urgent care operation and can adversely affect the core injury/illness business.</li> <li>• Although insurers are highly motivated to minimize the costly long-term expense of HIV care, many contracts will not reimburse what they consider a primary care service (PrEP) performed at an urgent care center.</li> </ul>

like PrEP can give people the idea that contracting HIV isn't the harbinger of doom it once was and encourage increased risk-taking that would result in higher numbers of STD/Is. This concern is supported by a recent study commissioned by clinicians in Montreal, Canada of STD/I infection rates among gay and bisexual males who were taking PrEP.<sup>9</sup>

The study found that gay and bisexual men who regularly attend an LGBTQ health clinic in Montreal and were taking Truvada were 72% more likely to contract an STD/I than they were before beginning PrEP. The study took place over a 12-month period, and found that rates of anal chlamydia doubled among the men in the study, with cases of gonorrhea and syphilis rising as well, albeit to a lesser degree.

So what are main risks that health researchers found that PrEP users are more likely to take? There are several:

- Decreases in the likelihood that people would *serosort*, or use a partner's HIV-status as a determining factor in deciding to engage in sexual behavior
- Increases in the likelihood of engaging in condomless anal sex
- Increases in the number of sexual partners
- Increases in needle-sharing

In short, PrEP critics fear that a lowering of sexual inhibitions and attitudes toward risky behaviors brought on

by the perceived protection of PrEP will lead to dramatic increases of STD/I infections nationwide. Experts point to increased gonorrhea resistance as a forewarning, which the CDC now reports only the antibiotic ceftriaxone (Rocephin) remains widely effective against. This has public health organizations and infectious disease experts working overtime to increase STD/I screenings, actively promote sexual health services, disseminate literature, and offer resources and support to head off a potentially larger STD/I problem down the road.

### Nonadherence

The other serious concern within the healthcare community regarding the widespread dispensing of PrEP is the consequences of nonadherence. That is, whenever a drug used as a treatment is also disseminated for prevention—especially under circumstances where adherence to strict dosing regimens cannot be monitored—resistance is becomes a strong possibility. Inevitably, this leads to HIV strains that are resistant to Truvada and drugs that function in a similar fashion.

So, what are the factors that can adversely influence nonadherence to PrEP? Healthcare professionals focus on two primary background causes:

- **Issues with adhering to a daily regimen of potentially harsh drugs** – Individuals and groups who

have a high risk of contracting HIV universally laud the ability of Truvada to save lives. But the reality is, for individuals who experience adverse health reactions to PrEP—including hair loss, nausea, vomiting, kidney and liver issues, and being bedridden for long periods—there will always be a strong temptation to skip doses.

■ **High-risk groups having the greatest risk factors for nonadherence** – Researchers consistently find that the groups most at risk to contract HIV are also the ones least likely to stick to the strict dosing roles. More often than not, these are individuals who face economic barriers and social circumstances that would act as obstacles to easily and regularly taking PrEP. These factors could include:

- Various social stigmas (ie, promiscuity, shame, “Truvada whore” label)
- Substance abuse issues leading to forgetfulness and lax adherence to daily medications
- Lack of reliable transportation to clinics, hospitals, and other healthcare facilities (ie, prescription renewals, testing, follow-up)
- Limited access to free PrEP for those without quality health insurance
- Sharing PrEP with their sexual partners
- Partner violence

The FDA, taking note of the various issues, tasked Gilead to develop a Risk Evaluation and Mitigation Strategy (REMS) to address these concerns. And although the REMS is making headway in educating Truvada users about the dangers of drug resistance, it does not specifically address all the factors that have been shown to influence nonadherence. Hence, the healthcare community at large continues to work on developing improved risk mitigation strategies, as the drug is still a relatively new HIV prevention method.

For the urgent care operator, **Table 2** addresses the pros and cons of administering PrEP in the urgent care setting.

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### Conclusion

Urgent care, already a well-established clinical option for STD/I treatment, has seen a number of centers begin offering HIV PrEP services. While many in the urgent care community see this expansion of treatment as an excellent way to increase revenues while providing much-needed healthcare services to the underserved LGBTQ community and others considered high-risk for contracting HIV, critics contend that the urgent care model is ill-equipped for the time-consuming counseling, screening, testing, and assessment necessary for safe and effective PrEP dispensing. Regardless, the number of urgent care operations that are successfully implementing PrEP services while continuing to thrive in their core injury/illness business is growing. And as these successful urgent care

operations grow in their understanding of PrEP and develop partnerships with PCPs, health clinics, and HIV prevention centers; develop standardized protocols; and learn how to counsel and educate patients, they’ll continue to lay a solid groundwork for other centers to follow. ■

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