



Action Guide



HIV PREVENTION: PRE-EXPOSURE PROPHYLAXIS (PREP)



The Value Transformation Framework (VTF)

is designed to guide

health center systems change and can be applied to evidence-based HIV prevention and care. The VTF serves as an organizing framework with action steps that drive improved health outcomes, improved patient and staff experiences, reduced costs, and equity (Quintuple Aim).

WHY

is attention to PrEP and nPEP adherence and retention so important?

Pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) are medications used to prevent human immunodeficiency virus (HIV) acquisition. PrEP is a daily antiretroviral medication that prevents up to 99% of HIV infections for at-risk populations when taken as directed, and nPEP is indicated in emergent cases ≤ 72 hours following a possible or known exposure to HIV outside work settings^{1,2}.

HIV remains a significant public health crisis in the United States (U.S.), especially for traditionally marginalized populations, including men who have sex with men (MSM), transgender women (TGW), people who inject drugs (PWID), and people of color. Approximately 1.2 million Americans are currently living with HIV^{3,4}, though the Centers for Disease Control and Prevention (CDC) reports that the annual number and rate of diagnoses of HIV infection decreased 7% and 8%, respectively, in 2021 compared with 2017.

Decreases in HIV infection were noted in individuals 13-24 years of age and individuals 45 years of age and older⁴. Though promising, the numbers remain far lower than the projected goals of the [End of the Epidemic by 2030 Framework](#), highlighting the need for increased uptake in prevention strategies. Screening programs were disrupted by the COVID-19 pandemic, contributing to a decrease in HIV diagnoses in the U.S. and worldwide, underscoring the need to revive HIV prevention efforts^{4,5}.

In 2021, MSM accounted for 67% of new HIV infections⁴. African American and Latinx MSM represent the two highest-risk sub-populations, with 8,883 and 8,000 new HIV infections, respectively, accounting for roughly 57% of HIV infections among MSM⁴. African American MSM have a 50 percent lifetime chance of acquiring HIV; Latinx MSM have a 25 percent chance of contracting HIV⁶.



This Evidence-Based Companion Guide on Pre-exposure Prophylaxis (PrEP) and Non-occupational Post-Exposure Prophylaxis (nPEP) explores the steps to prevent the acquisition of HIV in at-risk populations and support and monitor medication adherence. Used alongside the Evidence-Based Care Action Guide, it offers health centers an actionable roadmap for HIV prevention within the context of whole-person care.



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The goal of PrEP is to prevent the acquisition of HIV and its associated morbidity, mortality, and burden upon individuals and society. PrEP is highly effective at preventing new HIV infections when taken consistently⁷. But suboptimal medication adherence can be pervasive, undermining PrEP's utility. Clinical implementation data indicates PrEP adherence is generally low and discontinuation rates are high⁸⁻¹⁰. Likewise, PrEP adherence is lower among people of color, thereby exacerbating inequities in HIV incidence and PrEP uptake^{10,11}.

Similarly, poor retention in care, or low "PrEP persistence," prevents providers from addressing barriers to adherence and offering supportive strategies for at-risk patients. Several PrEP studies demonstrate PrEP persistence is suboptimal across sub-populations¹²⁻¹⁴. Studies have shown that HIV incidence is higher among those not retained on PrEP versus those never initiated on PrEP, highlighting the importance of supporting individuals to stay in care over time, even months or years after PrEP initiation^{11,15}.

Community health centers are uniquely positioned to champion HIV prevention efforts by educating clinicians and patients about tools like PrEP. More than 30 million people receive services at community health centers, approximately 80% of whom are uninsured or publicly insured and 63% of whom are members of racial/ethnic minorities¹⁶. Through heightened awareness of HIV prevention tools, identifying at-risk populations, and fostering PrEP adherence and persistence, health centers can ensure medications like PrEP work effectively to mitigate new infections and contribute to national HIV prevention efforts. This is further supported by the *Ending the HIV Epidemic: A Plan for America (EHE)* initiative that specifically identifies community health centers as a primary distribution site within the four pillars of action to end HIV in the U.S.¹⁷.

WHAT

are the current clinical guidelines for managing PrEP adherence and retention?



The August 2023 United States Preventive Services Task Force (USPSTF) guidelines give a 'Grade A' - its highest endorsement - to the recommendation that providers offer PrEP to all individuals at risk of HIV acquisition³. The [USPSTF Recommendations](#) are that clinicians prescribe pre-exposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV infection. Moreover, they stress the importance of adherence in determining PrEP effectiveness. Upon review of the evidence, the USPSTF concluded that:

PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use. The USPSTF also found convincing evidence that adherence to PrEP is highly correlated with its efficacy in preventing the acquisition of HIV infection³.

Medications currently approved by the US Food and Drug Administration (FDA) for the use as PrEP³ include:

- Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and injectable cabotegravir are approved for use in at-risk adults and adolescents weighing at least 35 kg (77 lb) to reduce the risk of sexually acquired HIV.
- Oral TAF/FTC is approved for use in at-risk adults and adolescents weighing at least 35 kg (77 lb) to reduce the risk of sexually acquired HIV, excluding individuals at risk from receptive vaginal sex.
- No PrEP medications have FDA approval for the indication of reducing the risk of acquiring HIV via injection drug use, but Centers for Disease Control and Prevention (CDC) guidelines note that persons who inject drugs are likely to benefit from PrEP with any FDA-approved PrEP medication.



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The CDC also emphasizes the importance of adherence and retention in maximizing PrEP outcomes. In the [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2021 Update: A Clinical Practice Guideline](#), the CDC recommends daily PrEP with follow-up visits at least every three months⁶. For patients newly initiating daily PrEP, providers should educate patients regarding the importance of high adherence. Side effects can lead to non-adherence, so clinicians should discuss potential side effects with newly initiating patients and develop contingency plans to ensure consistent adherence. At follow-up visits, clinicians should provide medication adherence counseling and behavioral risk reduction support in conjunction with HIV, sexually transmitted infection (STI) testing, and other health services.

▶ PrEP ADHERENCE AND RETENTION MANAGEMENT

While self-reporting (i.e., asking the patient how often they are taking their medicine) is the most widely used method of assessing medication adherence, it is subject to bias, and several studies note a discrepancy between self-reported PrEP adherence and actual PrEP adherence⁸. Objective adherence monitoring using bio-markers (e.g., urine or blood) to test the concentration of PrEP drug components can be crucial in targeting medication adherence support to those who need it most. Numerous scientific studies have noted a protective effect of certain drug concentrations in plasma, urine, hair, and dried blood spot⁸. Innovations in biomarker-based objective adherence monitoring, especially urine-based methods, allow for more routine application in ambulatory settings such as health centers.

▶ EVIDENCE-BASED PrEP ADHERENCE STRATEGIES

Evidence-based approaches that support medication adherence include patient education on mechanisms of action; discussing, anticipating, and mitigating side-effects; and asking about adherence patterns at follow-up visits (e.g., successes, challenges)⁶. Additionally, health centers can assist patients in establishing dosing routines that align with their schedule, suggest helpful medication reminder tools, address financial barriers, assess for substance use disorder or mental health needs that may impede adherence, and link patients to support systems and services. Data from PrEP studies observed lower adherence among younger MSM when visits occurred every three months but higher adherence with monthly visits⁶.

Considering FDA approval (2021) of cabotegravir (CAB) injections every two months as an alternative to daily pills for PrEP, health centers should inform patients of all FDA-approved treatments when discussing PrEP⁶. CAB may be especially appropriate for patients with significant renal disease, those who have had difficulty with adherent use of oral PrEP, and those who prefer injections every two months to an oral PrEP dosing schedule. Providers should not administer CAB to persons with a known history of hypersensitive reactions to cabotegravir.

CAB guidelines can be found within the 2021 PrEP [Clinical Practice Guidelines](#).

Probing medication adherence example:

"Some people find it difficult to take medication every day. Thinking about the last week, how many days have you not taken your medication?"⁶





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HOW

can health centers impact PrEP adherence and retention?

Health centers play an integral role in ensuring that PrEP works effectively for those at the greatest risk of HIV acquisition. Nevertheless, supporting patients to sustain medication and appointment adherence requires buy-in from stakeholders at all levels of the organization. Holistic support services are needed to ensure patients remain adherent and retained in care.

Health centers can use the following five action steps to optimize the efficacy of their PrEP program.

SUMMARY

HIV PREVENTION (PREP) ACTION STEPS

- STEP 1** **Engage leadership:** Make adherence and retention an organizational priority and focal point of the health center’s PrEP program with buy-in from leadership.
- STEP 2** **Adopt and implement an objective adherence monitoring and support protocol:** Use the protocol to facilitate the allocation of patient-level adherence support services.
- STEP 3** **Use adherence data to identify patients at risk of future non-retention (patient-level):** Segment your patient population into target groups needing PrEP retention support services.
- STEP 4** **Monitor trends in adherence across patients and demographics (clinic-level):** Use the data generated by adherence testing to improve the quality of PrEP services.
- STEP 5** **Maximize reimbursement for adherence and retention support services:** Identify the billing codes that correspond with PrEP testing and support services and train staff on utilizing them.

STEP 1 Engage leadership.

The first step in improving PrEP outcomes across your health center’s PrEP population is building consensus within the organization regarding the importance of PrEP adherence and retention. Name a clinical lead who is responsible for managing activities related to PrEP adherence and retention. Ensure that leadership supports this staff member through messaging, dedicated time, and additional resources to carry out necessary activities.

In conjunction with leadership, set short-term and long-term PrEP adherence and retention targets. Short-term targets include training staff and updating PrEP care protocols. Long-term targets include 6-month and 12-month adherence and retention metrics across PrEP patients.



Action Item: Leadership acknowledges PrEP adherence and retention as a priority and updates the broader health center strategy to include this new priority.

Appoint a PrEP adherence and retention clinical lead and work with leadership to set benchmarks for success.



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STEP 2

Adopt and implement an objective adherence monitoring and support protocol.

Identify patients needing enhanced adherence and retention support services. This can include integrating routine objective adherence testing into the health center's standard PrEP clinical workflow.

Biomarker-based methods of assessing adherence to PrEP (e.g., urine-based adherence testing or dried blood spot) can objectively identify non-adherent patients and link them to adherence support services. Urine-based testing – an indicator of recent PrEP adherence – is noninvasive and can be implemented alongside STI testing. Dried blood spot testing – an indicator of long-term PrEP adherence – requires only a fingerstick and can be collected during routine appointments.

For patients needing support with adherence, clinicians can employ integrated motivational interviewing and informed choice counseling. For example, Integrated Next Step Counseling (iNSC) is an evidence-based approach to improve adherence, which entails²²:

- Share adherence test results in a non-judgmental manner;
- Discuss barriers to adherence; and
- Brainstorm solutions to improve adherence.

iNSC research offers a [Process Map](#) for clinicians to implement in clinical practice when interfacing with populations indicated for PrEP. iNSC paired with a biomarker-based method of assessing PrEP adherence generated a 50% improvement in PrEP adherence in a 2017 study¹⁸.

Use the patient portal available through your existing electronic medical record or through an external patient-centric and PrEP-specific vendor (e.g., Healthvana, PlushCare, or MISTR) to provide diagnostic results directly to your patients. These tools can effectively increase patient engagement in care and improve adherence and retention.



Action Item: Leadership and PrEP leads should update clinical protocols or standard operating procedures to include routine objective adherence monitoring and support services for all patients on PrEP. Once updated, train staff on how to conduct adherence testing and provide Integrated Next Step Counseling (iNSC) to patients needing adherence support.

STEP 3

Use adherence data to identify patients at risk for future non-retention (patient-level).

Develop processes to in addition to identifying patients who are not consistently taking PrEP, objective adherence testing can identify patients at risk of dropping out of care. Research shows that patients who do not take PrEP, have low adherence with PrEP, or discontinue PrEP, are more likely to drop out of care than patients taking PrEP⁸. As health centers roll out objective adherence testing to PrEP patients, they should ensure that non-adherent patients receive support services to bolster adherence and PrEP retention.

Create patient tracking and outreach systems to monitor and improve PrEP retention. Update databases and electronic medical records to track previous adherence status and appointment attendance performance. Create automated registries of patients at higher risk for non-retention and target outreach efforts to minimize loss-to-follow-up. Targeted outreach activities can include the following:

- Send monthly appointment reminders
- Call patients the week before the appointment



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- Ensure staff are available to communicate with patients in between appointments
- Implement an app-based portal that provides direct contact between staff and patients to facilitate communication around retention support and increase the likelihood of keeping individuals in care¹⁹.



Action Item: Create a registry of patients who previously refused, discontinued, or had low adherence with PrEP and allocate additional support services to ensure they present for their scheduled clinic visits.

STEP 4

Monitor trends in adherence across patients and demographics (clinic-level).

Track patient- and clinic-level adherence and retention metrics, including but not limited to:

- Overall adherence rates across the health center, disaggregated by race, ethnicity, sexual orientation, sex assigned at birth, and gender.
- Patient adherence trends since PrEP initiation.
- Proportion of patients not taking PrEP as prescribed who demonstrate adherence at their next appointment after receiving adherence support services.
- Appointment attendance rates.
- 3-, 6-, and 12-month retention-in-care rates.

Health centers can translate this data into reporting metrics for leadership, allowing them to refine benchmarks based on organizational performance.



Action Item: Regularly monitor adherence and retention trends, identify patients and sub-populations at greater risk, and adjust support services to improve performance across the health center.

STEP 5

Maximize reimbursement for adherence and retention support services.

Prior to receiving a prescription for PrEP, a patient will require counseling and lab testing. Insurers will generally reimburse a health center for medically necessary routine PrEP adherence testing and counseling when provided by a physician, advanced practice registered nurse practitioner (APRN) or a physician assistant (PA). For follow-up visits, offer counseling for risk reduction, medication management adherence, and adherence testing. There are no official billing codes for PrEP, so it is important to follow payer policies in order to comply with their requirements and to receive reimbursement. The laboratory testing associated with PrEP initiation and adherence involves screening tests that are sent to commercial laboratories and not included in this guide.

The appropriate ICD-10-CM diagnosis code must be linked to the CPT service code.

ICD-10-CM Diagnosis Codes

The practitioner indicates the reason for the visit when initiating PrEP and/or for PrEP adherence visits. The most appropriate ICD-10-CM codes for services related to PrEP are found in the W or Z Codes category of the manual. The W category, found in Chapter 20 of the manual, includes diagnoses pertaining to “External Causes of Morbidity”. The Z category, found in Chapter 21 of the manual, is titled “Factors including health status and contact with health services (Z00-Z99).”



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The more frequently used ICD-10-CM codes include:

ICD-10-CM CODE*	DESCRIPTION	WHEN IT IS USED
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	Visit to initiate PrEP
Z11.4	Encounter for screening for HIV	Visit to initiate PrEP or anytime testing for HIV is indicated
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transitions	Screening for nonspecific tests other than HIV or HPV
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids	Visit to initiate PrEP
W46	Contact with hypodermic needle (see manual to select appropriate numeric digits)	Visit to initiate PrEP
Z51.81	Encounter for therapeutic drug level monitoring	Use for PrEP monitoring; also used to code for longer-term drug therapy Z79.899
Z79.899	Other long term (current) drug therapy	Use for PrEP monitoring

*American Medical Association, CPT® 2023 Professional Edition.

Additional category “Z” diagnosis codes may be found in Chapter 21 of the ICD-10-CM manual. If a patient’s exposure risk is related to their drug dependence or abuse, then a secondary diagnosis code from the “F11” Category of the ICD-10-CM manual would be indicated. There are currently no ICD-10-CM diagnosis codes specific to intravenous drug use. See Chapter 5 of the manual for more information.

CPT Service Codes

Most often, payers will require physicians, APRNs, and PAs to use an office visit (E/M) code to initiate PrEP and preventive medicine service codes for a preventive history and physical and for counseling related to behavior and other risk reduction. While Medicare will reimburse FQHCs for individual counseling services they will not reimburse for group sessions.

CPT CODE	DESCRIPTION	WHEN IT IS USED
99202-99205	Office or other outpatient service (new patient) level selected based upon time or medical decision making.	Initiating PrEP and/or where education and limited counseling is provided to a new patient.
99212-99215*	Office or other outpatient service (established patient) level selected based upon time or medical decision making.	Initiating PrEP and/or where education and limited counseling is provided to an established patient.
99401-99404**	Preventive medicine counseling services to an individual for risk factor reduction in patients without a known disease. Code selection is based upon the time the practitioner spends with the patient.	Initiating PrEP or for counseling and risk factor reduction intervention. Counseling may be separate from a follow-up medical office visit.



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99411-99412***	Preventive medicine counseling services to an individual in a group setting for risk factor reduction in patients without a known disease. Code selection is based upon the time the practitioner spends with the patient.	Counseling and risk factor reduction intervention as part of PreEP adherence services.
98960-98962****	Self-management education and training 1-8 patients.	To teach the patient how to self-manage for the purpose of preventing illness.

*Medicare and Medicaid typically do not reimburse FQHCs for CPT 99211 services (non-physician office visit) so it has been omitted from this table.

** Refer to the CPT Manual for the time associated with the services in code range 99401-99404. Services may be provided on the same day as a medically necessary, separately identifiable E/M service with modifier 25 appended to the E/M code.

*** Medicare, and some Medicaid programs, do not reimburse FQHCs for counseling in group settings. Services may be provided on the same day as a medically necessary, separately identifiable E/M service with modifier 25 appended to the E/M code.

**** Refer to the CPT Manual for the number of patients associated with the services in code range 98960-98962. Community Health Workers or other non-licensed professionals may be able to furnish these services depending upon state license and scope of practice limitations and payer policies. Many payers currently do not pay for these services. General supervision is typically required to be provided by a physician, APRN, or PA depending upon the state.

Additional Category II Codes from the CPT manual may be required by payers for quality reporting to identify therapeutic, preventive, or other inventions.

- 4276F: Potent antiretroviral therapy prescribed (HIV)
- 4270F: Patient receiving potent antiretroviral therapy for ≥6 months (HIV)
- 4290F: Patient screened for injection drug use (HIV)
- 4293F: Patient screened for high-risk sexual behavior (HIV)



Action Item: Identify sources of reimbursement for HIV prevention, PrEP adherence testing, and support services; train staff on how to incorporate these billing codes into the electronic medical record and billing systems.

► ON-DEMAND PrEP

Some providers and health departments are offering guidance for 'on-demand' PrEP as an alternative to daily PrEP. There is some evidence to suggest that a 2-1-1 schedule (taking 2 pills 2-24 hours before sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose) provides protection for gay and bisexual men when having anal sex without a condom. There is no data on how this schedule works for heterosexual men and women, people who inject drugs, and transgender persons.²³ On-demand is not approved by the FDA and is not recommended by the CDC.²³

► NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP)

Non-occupational post-exposure prophylaxis (nPEP) is an antiretroviral medication given ≤72 hours after a possible or known HIV exposure that occurs outside work-related settings (e.g., isolated sexual event, sexual assault, injection drug use)²⁰. Occupational post-exposure prophylaxis (oPEP) would be indicated for possible/known exposures occurring within work settings. The information below outlines the best practices, evidence base, and resources for nPEP. The U.S. Public Health Service offers guidelines for managing occupational exposures to HIV and recommendations for post-exposure prophylaxis (oPEP), available [here](#).



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nPEP Best Practices

- Health care providers should evaluate persons rapidly for nPEP when care is sought ≤ 72 hours after a potential non-occupational exposure that presents a substantial risk for HIV acquisition²⁰.
- nPEP initiation should be considered in people whose vagina, rectum, eye, mouth, or other mucous membrane, nonintact, or perforated skin comes in contact with body fluids from a person with HIV, as long as exposure has occurred within a 72-hour window. If the source person or body fluids are of unknown HIV status, case-by-case determinations can be made when the reported exposure presents a substantial risk for transmission if the source did have HIV infection²⁰.
- All persons considered for nPEP should have a determination of their HIV infection status by HIV testing, preferably using rapid combined Ag/Ab or antibody blood tests²⁰.
- If rapid HIV blood test results are unavailable and nPEP is otherwise indicated, it should be initiated without delay and can be discontinued if the patient is later determined to have HIV²⁰.
- nPEP is not recommended when care is sought > 72 hours after potential exposure²⁰.
- All persons offered nPEP should be prescribed a 28-day, [3-drug antiretroviral regimen](#)
- All persons who report behaviors or situations that place them at risk for frequently recurring HIV exposures (e.g., injection drug use or sex without condoms) or who report receipt of ≥ 1 course of nPEP in the past year should be provided risk-reduction counseling and intervention services, including consideration of PrEP²⁰.
- People who are already adhering to a PrEP regimen under the care of their health care provider do not need nPEP²⁰.
- nPEP after exposures that carry a substantial risk for HIV infection requires prompt evaluation of patients and consideration of biomedical and behavioral interventions to address current and ongoing health risks²⁰.

nPEP Evidence Base

Because of ethical implications, no large-scale prospective randomized placebo-controlled nPEP clinical trials have taken place. However, there exists over a decade's worth of subject matter research that includes an evidence base of animal studies giving biologic plausibility; case-controlled studies demonstrating an 81% (95% confidence interval [CI] = 48%–94%) reduction in the odds of HIV transmission among health care workers with percutaneous exposure to HIV who received nPEP; and efficacious observational studies²¹.

nPEP Risks

There are a few contraindications to the recommended nPEP regimen. All medications in nPEP regimens have minimal drug-drug interactions. In nearly all cases, the first dose of a nPEP regimen should be initiated, with further consultation obtained thereafter²¹.

Because pregnancy has demonstrated increased susceptibility to sexual HIV acquisition, nPEP can be essential for pregnant persons. If the individual exposed to HIV is pregnant, expert consultation should be sought. In general, however, nPEP is indicated at any time during pregnancy when a significant exposure has occurred, despite a possible risk to the pregnant patient and the fetus. In this case, the recommended nPEP regimen remains the same²¹.

nPEP Resources

Further details, including algorithms for patient management and nPEP pharmacology, are available in the following guidelines:

CPG: [Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016 \(cdc.gov\)](#)

CDC: [PEP Brochure for Health Providers](#)



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