Public Health – Seattle & King County
Preexposure Prophylaxis (PrEP) Implementation Guidelines 2025

These guidelines update PHSKC guidance issued in 2024 related to HIV PrEP implementation and are designed to complement the US Public Health Service and IAS-USA PrEP guidelines.[1,2] They reflect information that was not available when national guidelines were developed as well as issues related to cost, local epidemiology, and implementation. Important changes from the 2024 guidelines are highlighted in Box 1.

Box 1. Interval changes from 2024 guidelines

- HIV and syphilis screening interval extended to 6 months for most oral PrEP users on a stable oral PrEP regimen for ≥6 months
- Recommendation not to stop PrEP in patients who do not follow up as recommended
- Routine screening for asymptomatic gonorrhea and chlamydial infection is no longer recommended in people without a uterus who have sex with men. PHSKC advises medical providers to discuss gonorrhea and chlamydial screening with patients and use shared decision-making to decide whether to screen asymptomatic people for these infections. This change is based on:
  - ❖ The absence of known sequelae associated with asymptomatic infections,
  - ❖ The fact that these infections are self-limited in the absence of treatment,
  - ❖ The uncertain impact of screening on population-level STI incidence, and
  - ❖ To avoid the unnecessary use of antimicrobials.
- Updated information on considerations for TAF/FTC use in cisgender women and use of lenacapavir for PrEP in all populations with sexual exposures

Approximately 70% of all persons with HIV infection in Washington State and in King County are men who have sex with men (MSM), over 50% of new HIV infections occur in MSM, and MSM are the primary candidate population for PrEP use in the area. MSM who are young, Black, Indigenous, unhoused, and/or who use methamphetamine have the lowest levels of PrEP use and lowest rates of PrEP persistence (continued use) following initiation.

Identifying persons to consider for PrEP:

- Public Health recommends that medical providers routinely ask all adolescent and adult patients about the gender of their sex partners.
- Providers should ensure that all their patients who are MSM, transgender or non-binary (TNB) and have any sex partners with a penis know about PrEP.

Analyses of local data suggest that the strongest risk factors for HIV acquisition among MSM are methamphetamine use, condomless receptive anal sex in the prior year, having >10 sex partners in the prior year, and a history of gonorrhea or syphilis in the prior year,[3] and these analyses have helped inform local guideline development. Local MSM with one of these risk factors have an annual HIV incidence of 0.5-1%, with higher incidence observed in men with more than one risk factor.

Guidelines for initiating HIV PrEP:

Medical providers should recommend that patients initiate PrEP if they meet the following criteria:

1) MSM or TNB persons who have sex with men (or any partners with a penis) and have one or more of the following risks in the prior 12 months:
   a. Diagnosis of gonorrhea or early syphilis
   b. Methamphetamine use
   c. Condomless receptive anal sex with someone other than a mutually monogamous partner
   d. >10 sex partners
   e. Trading sex for money, drugs, housing, or other things of value
2) Persons in ongoing sexual relationships with a partner living with HIV who is not on antiretroviral therapy (ART), **OR** is on ART but is not virologically suppressed **OR** who is within 2 months of initiating ART.

Medical providers should discuss initiating PrEP with any person seeking a prescription for PrEP or based on any of the following current or anticipated risk factors:

1) MSM and TNB persons who have sex with men (or any partners with a penis) outside of a long-term, mutually monogamous relationship with another HIV-negative person
2) Persons in HIV-serodifferent relationships who are planning to conceive
3) Women who trade sex for money, drugs, housing, or other things of value
4) Persons who inject drugs and/or who use methamphetamine or opioids that are not prescribed by a medical provider
5) Persons diagnosed with syphilis
6) Persons who have sex at commercial sex venues or in party environments which are also sex venues
7) Sex partners of persons with any of the above risk factors
8) Persons in ongoing sexual relationships with partners living with HIV who are on antiretroviral therapy and virologically suppressed. (Note: If a person with HIV is virologically suppressed, they cannot transmit HIV to others through sex. This concept is known as undetectable equals untransmittable or U=U.[4] All PrEP patients should be informed about U=U. U=U does not apply to nonsexual routes of transmission, such as the sharing of equipment for drug injection. Some HIV-negative people who have partners with well-controlled HIV may feel more comfortable taking PrEP and thus should be offered it.)

CDC guidelines recommend discussing PrEP with all sexually active patients, but this is often not feasible given constraints on clinician time, and in many clinical settings most patients are at low risk for HIV. Beyond the patients with the characteristics listed above, PHSKC recommends that medical providers use their clinical judgement to determine with whom to discuss and prescribe PrEP.

Patients should decide together with their medical providers what prevention strategies are best for them. Providers should evaluate patient's knowledge about the various PrEP use strategies and should counsel and educate patients to facilitate their success on PrEP. The most recent CDC practice guidelines and the National HIV PrEP Curriculum (hivprep.uw.edu) provide detailed information on how to prescribe PrEP and monitor persons on PrEP.

PrEP prescribing, follow up and continuation

In the absence of clinical signs or symptoms of HIV infection (including acute HIV), medical providers should not wait to receive negative HIV tests results before prescribing PrEP. It is safe to provide patients with PrEP on the same day as their clinical evaluation if the following criteria are met: **1)** blood is collected and sent for lab-based HIV antigen/antibody testing or such a test was negative within the last 2-4 weeks with no recent concerning HIV exposures, and **2)** creatinine and hepatitis B serostatus are already known or blood is collected and sent for these tests, and **3)** results will be available within 7 days and the provider can contact the patient if their HIV test is positive. If possible, patients should also undergo HIV testing with a blood-based (not oral fluid testing) point of care rapid HIV test on the day of their clinical evaluation prior to receiving a PrEP prescription. Of note, the lack of availability of HIV RNA testing should not be a limiting factor in prescribing oral PrEP. Patients who test positive for HIV and are confirmed to have HIV infection should be given a full HIV treatment regimen as recommended in national guidelines.[5] PHSKC recommends that medical providers prescribe patients 90 days of PrEP at their initial visit.

Medical providers should consider following up with patients at 1-2 months following PrEP initiation to inquire about side effects and adherence; this can be done by telephone, telemedicine visit or secure messaging. However, this should not be a requirement for continuing PrEP.

Patients on oral PrEP should be tested for HIV and syphilis every 3-6 months, with the preferred option being every 6 months for persons on a stable PrEP regimen for ≥6 months. PHSKC advises against stopping PrEP in patients who miss HIV/STI testing appointments as PrEP discontinuation increases the risk of HIV acquisition.[6] It is reasonable to allow up to 12 months without testing before considering discontinuation of oral PrEP refills.

Although PHSKC previously recommended that MSM and TNB persons on PrEP be screened for gonorrhea and chlamydia every 3-6 months, recent evidence suggests that screening has a very limited impact on the incidence of symptomatic gonorrhea and chlamydial infection.[7,8] The clinical and public health benefit of

treating infections that are self-limited and usually asymptomatic[9–11] in non-pregnant people is unclear. Considering this observation and to limit the unnecessary use of antimicrobials, PHSKC recommends that medical providers engage MSM and TNB patients in shared decision-making regarding whether and how often to screen for asymptomatic gonorrhea and chlamydia infections. Patients with symptoms concerning for gonorrhea or chlamydia and persons seeking care following contact to a sex partner with diagnosed gonorrhea or chlamydia should be tested for those infections. Patients who report contact to syphilis should be treated empirically at the time of testing. Patients who report contact to a partner with gonorrhea or chlamydial infection should be tested and engaged in a shared decision-making discussion on whether to treat them immediately or deferring treatment based on test results. Approximately two-thirds of people evaluated as contacts to gonorrhea or chlamydia are uninfected, with higher levels of infection observed in contacts who are cisgender women than cisgender men.[12–14]

Clinicians and their staff should implement procedures that make PrEP follow up simple and flexible. PHSKC endorses the use of standing orders for PrEP monitoring tests to allow patients to present to a laboratory for a blood draw and, when desired, self-sampling for gonorrhea and chlamydia screening without being seen by a medical provider.

PHSKC encourages providers and their staff to reach out to patients who discontinue PrEP to encourage follow up. Several community-based organizations have staff that can assist patients to stay on PrEP (https://doh.wa.gov/sites/default/files/2024-04/150083-PreventionServiceNavigationProviders.pdf).

In some cases, home-based self-collection of swabs and/or blood samples for laboratory-based testing may be an option for PrEP monitoring. However, there are some limitations to using commercial, direct-to-consumer companies for PrEP monitoring and STI screening. These may include the inability to perform quantitative RPR testing for persons with a history of syphilis, promotion of inappropriate or unnecessary testing for non-pathogenic organisms (e.g., *Ureaplasma*), and additional out-of-pocket costs to the patient.

PrEP Regimens

Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC). Given the high efficacy of TDF/FTC as PrEP,[15] local data demonstrating the drugs' high effectiveness,[16] evidence for use in multiple populations of all genders,[1] and the dramatic difference in cost between TDF/FTC and other PrEP regimens, PHSKC recommends that medical providers use daily generic TDF/FTC as the primary PrEP regimen and that other regimens should be used only if clinically indicated (Table 1). This recommendation is aligned with those of the New York City Department of Health and Mental Hygiene as well as published expert opinion.[2,17,18]

MSM and TNB people who primarily engage in insertive vaginal or any anal sex may also use TDF/FTC for event-driven PrEP (sometimes called on-demand, event-driven or 2-1-1 dosing);[2,19,20] this regimen may be particularly useful in persons who infrequently have condomless sex and can accurately predict when they will have sex.

Prospective efficacy data for event-driven PrEP in cisgender women are lacking. A recent modeling analysis using HPTN 067 study data from cisgender women in Cape Town estimated an effectiveness of 81% for daily TDF/FTC, 46% for time-based PrEP (2 pills/week + 1 pill after sex), 42% for event-based PrEP (1 pill before + 1 pill after sex), and 59% for standard 2-1-1 PrEP.[21] Thus, while daily oral TDF/FTC use is ideal and provides the highest level of protection, for women with low (<3 pills/week) adherence to daily oral PrEP, on-demand options may provide benefit by decreasing the number of days that pills need to be taken.

Tenofovir alafenamide (TAF/FTC). While TAF/FTC is efficacious in MSM and transgender women, it is not superior to TDF/FTC.[22] Both drugs have a low risk of adverse events, including nephrotoxicity. TDF/FTC is associated with small, reversible decreases in creatinine clearance (median difference in serum creatine 0.02 mg/dL at 48 weeks follow up) and measures of bone mineral density (median 1.62% change at 48 weeks follow up) relative to TAF/FTC, while TAF/FTC is associated with more weight gain (mean difference in weight change 2.64 lbs at 48 weeks) and slightly less favorable lipid parameters than TDF/FTC.[22] The average wholesale acquisition price for TAF/FTC is over 75 times higher than the cost of generic TDF/FTC,[23] though the prices different insurers pay varies. Given the minimal difference in clinical outcomes between the two

medications, TAF/FTC is not cost effective (estimated $7 million cost for a single year of life in perfect health) compared to TDF/FTC.[24]

Although a randomized trial of TAF/FTC PrEP in cisgender women did not demonstrate efficacy, an analysis that incorporated trial data on adherence reported that TAF/FTC was associated with an 89% reduction in HIV acquisition risk in cisgender women who took 2 or more doses per week.[25] A national panel of experts recently endorsed daily TAF/FTC as a PrEP option for people with vaginal exposures who cannot tolerate or take TDF/FTC.[26]

Prior to making a switch from TDF/FTC to TAF/FTC due to concerns about decreased renal function, serum creatinine and estimated glomerular filtration rate should be assessed at least twice to document a sustained decrease in renal function. Several factors may contribute to elevated creatinine levels, including increased muscle mass, use of creatine or some exercise supplements, nonsteroidal anti-inflammatory drug (NSAID) use, and hypovolemia. These factors should be assessed and corrected before obtaining and interpreting a repeat creatinine. Clinicians should consider obtaining a cystatin C with the repeat creatinine test to calculate a more accurate estimate of the glomerular filtration rate (GFR) (https://www.kidney.org/professionals/kdoqi/gfr_calculator). If the GFR is ≥60 mL/min, TDF/FTC should remain the recommended option for PrEP.

Long acting cabotegravir (CAB-LA). CAB-LA administered intramuscularly every 8 weeks was found to be more efficacious than daily TDF/FTC in a randomized trial conducted in a population at high risk for HIV composed of cisgender MSM and transgender persons (HPTN 083)[27] and in a randomized trial including people assigned female at birth aged 18-45 years in sub-Saharan Africa (HPTN 084).[28] Adverse events in the two study arms in both trials were similar. As is common in randomized trials, the study included extensive efforts to promote participant retention, including outreach and monetary incentives for study visits during which participants received medication; these procedures are not typically part of PrEP programs and the extent to which they influenced the study outcome is unknown. Retention on PrEP was 86% and 90%, respectively, at 12 months in HPTN 083 and 084. By comparison, retention in PrEP at 12 months in the PHSKC Sexual Health Clinic is approximately 60%.[29] Like TAF/FTC, CAB-LA costs over 75 times as much as generic TDF/FTC. Administering injectable CAB-LA can also present logistical challenges for busy clinics as it requires 6 visits per year (7 in the first year).

Lenacapavir (LEN). LEN administered subcutaneously every 6 months was found to be more efficacious than daily TDF/FTC in two randomized controlled trials, one conducted in adolescent girls and young cisgender women in Africa[30] and one conducted in cisgender men, transgender men, transgender women, and gender-nonbinary persons who have condomless receptive sex with partners assigned male at birth.[31] Like the CAB-LA discussed above, the study included extensive efforts to promote participant retention, including outreach and monetary incentives for study visits during which participants received medication; these procedures are not typically part of PrEP programs and the extent to which they influenced the study outcome is unknown. In the trials, retention on PrEP was 83-89% at 12 months.[30,31] The announced wholesale price of LEN, including the required oral lead-in doses, is approximately $30,000[32] – which like TAF/FTC and CAB-LA is over 75 times as much as generic TDF/FTC. Administering injectable LEN can also present logistical challenges for busy clinics, though these are likely to be less than for CAB-LA given its less frequent dosing schedule.

Table 1. PrEP Regimens, Clinical Indications and Approximate Costs

	Recommendation	Contraindications	Administration Route & Interval	Approximate Annual Cost*
Generic TDF/FTC	Preferred regimen to be used for most patients who desire PrEP**	Allergic reaction to TDF or FTC, CrCl <60 mL/min, osteoporosis	Oral Daily, 2-1-1, other on-demand	$350
TAF/FTC	Use in persons with the following indications:	Allergic reaction to TAF or FTC, CrCl <30 mL/min	Oral Daily	$26,424

	• Sustained CrCl 30-60 mL/min • Osteopenia or osteoporosis • Intolerance of TDF/FTC			
CAB-LA	Use in persons with one of the following indications: • Sustained CrCl <30 mL/min • Osteopenia or osteoporosis • Intolerance of TDF/FTC	Allergic reaction to cabotegravir	Intramuscular, 2 doses in first 28 days (optional oral lead-in) then every 2 months thereafter ——— 7 visits in first year	$27,720
LEN	Use in persons at high risk for HIV with one of the following indications: • Inability to consistently take or tolerate oral PrEP • CrCl 15-60mL/min[#] • Osteopenia or osteoporosis	Allergic to lenacapavir, CrCl <15 mL/min	Subcutaneous, every 6 months with required initial 2-day oral load ——— Twice annual visits	$30,569[¥]

All regimens are only approved for persons weighing at least 35 kg (77 lbs).
CrCl = creatinine clearance
* Based on wholesale acquisition costs
** Given the high cost of TAF/FTC, CAB-LA, and LEN, the decision to use one of these medications for PrEP should be based primarily on clinical indications (including the patient's life circumstances) and not patient preference alone
# LEN has not been studied in people with ESRD or on dialysis
¥ Estimated cost for 1st year including oral lead-in, after which annual cost is $28,218

Additional considerations
In the absence of a clinical indication for an alternative regimen, PHSKC recommends generic TDF/FTC as the primary PrEP regimen for most people. In general, patient preference alone is not an indication for using TAF/FTC, CAB-LA, or LEN. However, some patients at elevated risk for HIV infection face significant barriers to taking daily PrEP (e.g., houselessness, substance use, stigma, fear of partners or family knowing about their PrEP use) and, in some instances, CAB-LA or LEN is the best choice for such patients. (Because LEN is dosed less frequently than CAB-LA, at current pricing LEN is preferred over CAB-LA for most patients). Given disparities in rates of HIV and low levels of PrEP use and persistence among young, Black, and/or Indigenous MSM and TNB people, medical providers may opt to have a lower threshold for offering LEN or CAB-LA to patients from these populations. Public Health encourages healthcare organizations and medical providers to apply consistent criteria for using more expensive PrEP regimens to ensure their equitable use.

Medical providers should discuss doxycycline post-exposure prophylaxis with MSM and TNB persons for whom they prescribe PrEP and should recommend mpox immunization for patients who have not been previously immunized. PHSKC guidelines on the use doxy-PEP are available at https://cdn.kingcounty.gov/-/media/king-county/depts/dph/documents/health-safety/disease-illness/hiv-sti/doxypep-guidelines.pdf. Information on doxy-PEP from the WA DOH are available at https://doh.wa.gov/you-and-your-family/illness-and-disease-z/sexually-transmitted-infections-sti/doxycycline-postexposure-prophylaxis-doxy-pep

Additional resources:
The Washington State Department of Health may be able to provide financial assistance to help some patients pay for PrEP. As of January 1, 2025, per USPSTF recommendations, insurance payers should cover

laboratory testing and medication for PrEP with no cost share to the patient. Information about this program is available at: https://doh.wa.gov/you-and-your-family/illness-and-disease-z/hiv/prevention/pre-exposure-prophylaxis-drug-assistance-program-prep-dap

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