End HIV Oregon Toolkit:

HIV Pre-Exposure Prophylaxis (PrEP) Guide for Providers and Navigators: 2024 Update OCTOBER 2024





Contents

Purpose of this guide	L
PrEP overview	L
What is PrEP?	L
Who is PrEP for?1	L
Who can prescribe PrEP?	2
HIV and PrEP use in Oregon	2
PrEP clinical basics	1
Support for PrEP Providers	1
What medications are used for PrEP?	5
How quickly is PrEP effective?	7
Is PrEP safe?	3
Side effects and drug interactions	3
PrEP and hormone use)
PrEP and contraceptive use)
PrEP and conception, pregnancy, and breast/chestfeeding)
Opportunities for PrEP)
Transitioning from PEP to PrEP10)
Ancillary clinical services to accompany PrEP10)
Routine HIV testing10)
Baseline assessment for acute HIV infection or indication for HIV PEP11	L
Other sexual and reproductive health services11	L
Timeline of ancillary clinical services to accompany PrEP initiation, continuation, and discontinuation	2
Pharmacy prescribing of PrEP/PEP15	5
PrEP availability and access	5
Outreach navigation services	5
PrEP provider directory	5
PrEP coverage and payment assistance	7
Statutory and regulatory background17	7
Insurance plans and PrEP coverage17	7
Private insurance18	3
Medicaid/Oregon Health Plan (OHP)18	3

Medicare19
Patient assistance options for uninsured and underinsured patients
Appendix A: PrEP assessment flowsi
Assessing indications for PrEP in sexually active patientsi
Assessing indications for PrEP in patients who inject drugsii
Appendix B: Determination of HIV status for PrEP provisioniii
Clinician determination of HIV status for PrEP provision to persons without recent antiretroviral prophylaxis useiii
Clinician determination of HIV status for PrEP provision to persons with recent or ongoing antiretroviral prophylaxis useiv
Appendix C: Clinical Signs and Symptoms of Acute HIV Infectionv
Appendix D: IAS-USA Recommendations for PrEP by population, transmission behavior, and creatinine clearance – quick reference
Appendix E: PrEP drug interactionsvii
Oral PrEP medication drug interactionsvii
Cabotegravir PrEP drug interactions viii
Patient handout: frequently asked questions about PrEP access
Additional resources for providers and navigators

Purpose of this guide

Access to HIV Pre-Exposure Prophylaxis (PrEP) is a key component of Oregon's strategy to eliminate new HIV infections. Oregon funds our local health authorities and some community-based organizations to promote PrEP use and assist with PrEP navigation services. This guide is designed to help anyone interested in supporting people who want access to PrEP. Whether you are a pharmacist, clinician, or prevention specialist, this guide will provide the answers and resources you need to help people access PrEP information, services, and medication.

PrEP overview

What is PrEP?

PrEP is a medication taken to reduce the chances of getting HIV. It is a valuable tool to reduce a person's chance of acquiring HIV, along with viral suppression among people living with HIV, talking to partners about one's HIV status, and consistently using condoms and lubricants. PrEP is available as an oral pill or an intramuscular injection.

PrEP Q

Pre-exposure prophylaxis: medication taken by individuals who are HIV negative before a possible HIV exposure to reduce the risk of acquiring HIV.

PrEP does not provide protection against other sexually transmitted infections (STIs) or pregnancy and should therefore be paired with additional prevention tools as part of a patient's comprehensive sexual health plan.

When taken as directed, PrEP can reduce the risk of getting HIV through sex by more than 99% and can reduce the risk of getting HIV among people who inject drugs by up to 74%.

Who is PrEP for?

PrEP is for anyone who is HIV negative and who wants to reduce their chance of getting HIV. PrEP is recommended to prevent HIV among all people who may be exposed through sex or injection drug use, including adolescents.¹

All patients should be educated about PrEP as a part of comprehensive sexual healthcare assessment and counseling. Educating all sexually active patients about PrEP builds awareness of this highly effective HIV prevention tool and can help to reduce stigma and normalize PrEP use and conversations about HIV. Electronic health record prompts and PrEP promotional materials in patient waiting rooms are additional tools for building patient awareness of PrEP as one of many effective HIV prevention tools.

¹ PrEP is approved for use in patients weighing 77lbs or more, with no age cutoff.

In Oregon, minors of any age can access reproductive health care services and information from a licensed provider without parental or guardian consent.² This includes testing and treatment for HIV, syphilis, chlamydia, and gonorrhea, contraception, and any other health care or medical services related to reproductive health.³ Confidentiality concerns and policies should be discussed with minors seeking reproductive health services, including PrEP.

Stigma and embarrassment may prevent patients from fully disclosing sexual and drug use practices to their providers. To ensure that this does not impede

CDC recommends prescribing PrEP to anyone who asks for it, including sexually active adults and adolescents who do not report HIV risk factors.

access to PrEP, CDC recommends prescribing PrEP to any HIV-negative patient who asks for it (unless medically contraindicated). For guidance on assessing indications for PrEP, see the CDC assessment flows for sexually active patients and patients who inject drugs in Appendix A at the end of this guide or consult CDC's <u>Clinical Practice Guidelines</u> and <u>Clinical Providers'</u> <u>Supplement</u> on PrEP.

The choice of which PrEP medication to use should be the product of shared patient-provider decision making. Certain medications may be recommended based on personal factors including a patient's specific medical history, life circumstances, and preferences.

Who can prescribe PrEP?

Any health care provider licensed to write prescriptions can prescribe PrEP: in Oregon, that includes MDs, NPs, DOs, PAs, NDs, and some specially trained pharmacists. See the "Pharmacy prescribing of PrEP/PEP" section for more information on pharmacy-delivered PrEP services. Standing orders for PrEP initiation and continuation may also be used in nurse-run clinic settings, allowing RNs to deliver PrEP services.

Many resources are available for providers who would like to begin offering PrEP, including free trainings, guidelines, and clinical consultation services. See the "PrEP clinical basics" section and the "Additional resources for providers and navigators" section at the end of this document for more information.

HIV and PrEP use in Oregon

HIV continues to impact Oregonians across the state, including in rural and frontier areas. New HIV diagnoses decreased between 2012-2020 but have increased steadily since 2020. In 2022,

² Learn more about minor consent and confidentiality in Oregon here: <u>https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le9541.pdf</u> and <u>https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/SEXUALLYTRANSMITTEDDISEASE</u> /Documents/STI%20Minors%20Fact%20Sheet%202019.pdf

³ For a full definition of "reproductive health care" per Oregon law, see <u>ORS 435.190</u>

Oregon was home to 8,220 people⁴ living with HIV, including 244 Oregonians who were newly diagnosed with HIV.

Despite the U.S. Preventive Services Task Force (USPSTF) recommendation for routine, voluntary HIV screening among all adolescents and adults aged 15 to 65 years old, all pregnant persons, and all individuals at high risk of infection,⁵ lifetime HIV screening among Oregonians in 2022 was only 38% – not much higher than it was in 2012, at 34%. High rates of syphilis, gonorrhea, and viral hepatitis – often found as preceding infections and co-infections with HIV – further emphasize the need for ongoing HIV and STI prevention. Between 2017 and 2021, Oregon averaged about 202 new HIV cases each year.⁶ In 2022, 244 people were newly diagnosed with HIV in Oregon.

In Oregon and across the country, racial and ethnic inequities in infections persist.⁷ People living in Oregon who are Black/African American, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, and Hispanic or Latino/a/x/e have higher rates of HIV diagnosis than people living in Oregon who are white, multiracial, or Asian. Black/African American people living in Oregon face the highest rate of new HIV infections by race (20.1 per 100,000 people, compared to the overall state rate of 4.7 per 100,000 people).

Gay, bisexual, and other men who have sex with men (MSM) and transgender women are also disproportionately impacted by HIV.^{8,9} In 2022, MSM accounted for 67% of new HIV diagnoses in the nation and transgender women accounted for 2%.¹⁰ This over-representation is compounded for MSM and transgender women of color by the racial and ethnic inequities noted above. Structural factors including homophobia and transphobia contribute to barriers in access to testing, prevention, timely diagnosis, and treatment.

The root cause of Oregon's inequities in HIV is the systematic denial of rights and opportunities which impact optimal health for certain groups. Social and structural factors like access to healthcare, economic resources, rates of infection within one's social networks, rurality,

⁴ In 2022, there were 8,220 people diagnosed with HIV and living in Oregon. The Oregon Health Authority estimates that in 2022 there were about 1,110 additional people living with HIV in Oregon who had not yet been diagnosed.

⁵ USPSTF Final Recommendation Statement on HIV Screening, June 2019

⁶ See "Number of New HIV Diagnoses, 2008-2021" on the <u>AIDSVu Local Data: Oregon page</u>.

⁷ A note about reporting on race/ethnicity data: Race is a social construct and using racial categories to organize and understand variation can be misleading, harmful, and serve to pathologize and blame Black, Indigenous, and non-Black people of color and Tribal communities. We acknowledge that health equity can only be achieved when public health measurements of "race" do a better job at capturing the complex systems of economic, political, and social inequities that lead to ongoing disparities in health. Learn more about HIV inequities in Oregon on OHA's <u>HIV, STD & TB Section Data Dashboards</u>.

⁸ CDC STI Treatment Guidelines, 2021: Men Who Have Sex With Men

⁹ CDC STI Treatment Guidelines, 2021: Transgender and Gender Diverse Persons

¹⁰ U.S. Statistics from HIV.gov

segregation, racism, homophobia, transphobia, and stigma surrounding drug use – play critical roles in shaping inequities in HIV rates and outcomes. The root cause of these inequities is the systematic denial of rights and opportunities which impact optimal health for Black, Indigenous, and other people of color (BIPOC) and 2SLGBTQIA+¹¹ communities.

Although PrEP use in Oregon has increased, rates are still low. The number of new PrEP users dropped in 2020 after a steady increase between 2013-2019. Of the 244 individuals receiving a new diagnosis of HIV in 2022, 9.8% had ever used PrEP. PrEP users continue to be mainly white, cis-gender men who have sex with men who live in the Portland metropolitan area.

The PrEP-to-Need Ratio (PNR) is a nationally recognized metric calculated by dividing the number of PrEP users in a particular population by the number

All Oregonians should have equal access to PrEP information and services.

of new HIV diagnoses in that same population in the prior year. Per this metric, groups with higher rates of new HIV diagnoses are conceptualized as having a higher PrEP "need." A higher PNR, resulting from a larger number of PrEP users and/or a lower number of new HIV diagnoses, indicates improved HIV prevention. A comparison of PNRs across demographic groups illuminates how PrEP access across various groups measures up against the burden of HIV experienced by those groups.

Black/African American and Latino/a/x/e communities, people assigned female at birth, rural Oregonians, and young people have a lower PNR compared to the overall state PNR,¹² indicating a need for more effective HIV prevention tailored to the needs of these populations. Differences in PNR and PrEP use may be due to differences in awareness, access, or acceptability of PrEP within various populations. While PrEP is not appropriate or desirable for everyone, all people should have equal access to PrEP information and services to make informed decisions about their own sexual health.

PrEP clinical basics

This section introduces some clinical basics, such as PrEP medications, prescribing considerations, and ancillary clinical services to accompany PrEP initiation and continuation. Each of these topics are covered in greater detail in <u>CDC's PrEP Clinical Practice Guidelines.</u>

Support for PrEP Providers

Clinicians of any level of experience with PrEP prescribing may benefit from several essential resources:

¹¹ Two-spirit, lesbian, gay, bisexual, transgender, queer, questioning, intersex, asexual, and more

¹² More information about PNR and PrEP use in Oregon is available on the <u>End HIV Oregon Dashboard</u> and on the <u>AIDSVu Oregon Data</u> page.

PrEP Warmline

Clinicians may call <u>UCSF's</u> <u>National Clinician</u> <u>Consultation Center</u> PrEP Warmline at **855-448-7737** for a phone consultation.

- The warmline can provide advice on all aspects of PrEP, including initial and follow-up laboratory evaluations, follow-up and testing protocols, administering medications, addressing adherence issues, transitioning from PEP to PrEP, and more.
- Available Monday through Friday, 9am to 8pm EST.

Oregon AIDS Education & Training Center

The <u>Oregon AETC</u> offers clinical education and training to the medical community of Oregon and SW Washington.

Services include:

- One-on-one provider mentoring
- On-site provider education
- Communities of practice
- In-person and virtual group trainings

If you prescribe PrEP, please add yourself to the <u>PrEP</u> <u>Provider List</u>.

National PrEP Curriculum and PrEP Tools App

The National HIV PrEP

<u>Curriculum</u>, a free resource offered by the University of Washington, provides comprehensive material to support clinicians of all levels in developing proficiency with PrEP prescribing and management.

The <u>HIV PrEP Tools for</u>

<u>Clinicans App</u> provides support with evaluating patients for HIV PrEP, chosing appropriate HIV PrEP medications, and ordering recommended laboratory tests.

What medications are used for PrEP?

There are currently two FDA approved oral medications for PrEP and one FDA approved injectable medication for PrEP. The first-line regimen for PrEP is a two-drug fixed dose combination product containing tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC). This oral medication is abbreviated as TDF/FTC or F/TDF and is available under the brand name Truvada[®] or as a generic equivalent. TDF/FTC was FDA approved in 2012.

Generic TDF/FTC is appropriate for most patients and is an extremely costeffective option at about \$30 per month.

An alternate oral PrEP option is a twodrug fixed dose combination product containing tenofovir alafenamide fumarate (TAF) and emtricitabine (FTC). This medication is abbreviated

as TAF/FTC or F/TAF and is available under the brand name Descovy[®]. TAF/FTC was FDA approved in 2019. Descovy[®] is preferred for patients who may be exposed to HIV through anal sex and who have a non-isolated creatinine clearance between 30-60 mL/min or bone disease

risk factors. There are currently insufficient clinical data to determine its appropriateness for preventing HIV in individuals who may be exposed to HIV through vaginal/front hole sex and through injection drug use.¹³

Some patients may express a preference for Descovy[®] due to its smaller tablet size than TDF/FTC. No generic equivalent for Descovy[®] is currently available. Descovy[®] is significantly more expensive than generic TDF/FTC and can be challenging to get covered by insurance – however, financial assistance programs can help (see the "Patient assistance options for uninsured and underinsured patients" section for details).

Both oral PrEP medications are taken as a single daily pill. TDF/FTC may also be used for 2-1-1 dosing, an off-label use of PrEP for patients who may only need occasional protection. 2-1-1 dosing is also known as on-demand, event-driven, intermittent, or vacation PrEP. 2-1-1 dosing is not currently FDA approved – however, available data support use of 2-1-1 PrEP for men who have sex with men who may be exposed to HIV through anal sex. Currently there are insufficient data to determine whether 2-1-1 PrEP provides effective protection against other types of exposures such as vaginal/front hole sex and injection drug use.

An injectable version of PrEP, called Apretude[®] (cabotegravir extended-release injectable suspension, or CAB-LA) was also approved by the FDA in December 2021. Injectable PrEP is given intramuscularly, first in two initiation injections given one month apart, and then injections every two months. Vocabria[®] (cabotegravir tablets) may be optionally used as a 28-day oral lead-in to the first initiation injection of Apretude[®], to assess medication tolerability, although this is not commonly done. If oral lead-in is used, the first injection should be administered on the last day of the oral lead-in or within 3 days thereafter. No generic equivalent for Apretude[®] is currently available. Apretude[®] is currently the most expensive PrEP option and can be challenging to get covered by insurance – however, financial assistance programs can help (see the "Patient assistance options for uninsured and underinsured patients" section for details).

The table below outlines differences between PrEP medications that patients and providers should consider when selecting the best option for the patient. Descovy[®] is a newer medication than Truvada[®] and there are currently insufficient clinical data to determine its appropriateness for on-demand dosing.

¹³ As of April 2024, efficacy studies of Descovy among those who may be exposed to HIV through receptive vaginal/front hole sex are ongoing. Follow this, and other PrEP development research, at <u>AVAC.org</u> and <u>PrEPWatch.org</u>.

Medication Name	Route and Frequency of Administration	Recommendations for Use: Patient Population and Transmission Profile		
TDF/FTC (Truvada® or generic equivalent)	 ✓ Daily oral pill ✓ On-demand use 	✓ Any adolescent or adult, of any sex or gender, weighing at least 77lbs, with creatinine clearance >60.	Shown to be effective for people who may be exposed to HIV through:	
TAF/FTC (Descovy®)	✓ Daily oral pill Insufficient data to support on- demand use	✓ Any adolescent or adult, of any sex or gender, weighing at least 77lbs, with creatinine clearance >30.	Shown to be effective for people who may be exposed to HIV through: ✓ Anal sex Insufficient data to recommend to people who may be exposed to HIV through: • Vaginal/front hole sex • Injection drug use	
Cabotegravir (Apretude [®] and Vocabria [®])	 ✓ Intramuscular injection every other month following two injections given one month apart and an optional 28-day daily oral pill lead-in ✗ Not for on- demand use (must be administered by a healthcare provider) 	✓ Any adolescent or adult, of any sex or gender, weighing at least 77lbs, with no restrictions on creatinine clearance.	Shown to be effective for people who may be exposed to HIV through: ✓ Vaginal/front hole sex ✓ Anal sex ✓ Injection drug use ¹⁴	

How quickly is PrEP effective?

Current US guidelines suggest that oral PrEP, when taken daily, will provide maximum protection against HIV infection from receptive anal sex after 7 days and maximum protection

¹⁴ Cabotegravir is recommended for individuals who may be exposed to HIV through injection drug use *and* sexual activity. Data are not yet available on the efficacy of cabotegravir PrEP for people for whom the only potential route of HIV exposure is injection drug use.

against HIV infection from receptive vaginal/front hole sex and injection drug use after 21 days. Data are not available regarding time to protective levels for insertive sex.

On-demand PrEP is an off-label use of TDF/FTC (Truvada[®] or generic) that has been shown to be effective for men who have sex with men who may be exposed to HIV through anal sex.¹⁵ Currently there are insufficient data to determine whether on-demand PrEP provides effective protection against other types of exposures such as vaginal/front hole sex and injection drug use. This use of PrEP involves taking 2 pills 2-24 hours before sex, followed by 1 pill 24 hours after the first dose and 1 pill 24 hours after the second dose. On-demand PrEP may be suitable for patients who only need occasional protection and who are able to anticipate and/or delay sex to correctly time the 2-1-1 dosing regimen.

There are limited data on time to maximum protection against HIV with long-acting injectable PrEP; available evidence suggests that maximum protection is reached 7 days after the initial injection.

Is PrEP safe?

Side effects and drug interactions

PrEP is very safe and effective in lowering a person's chance of acquiring HIV. While many people contemplating PrEP are concerned about side effects, side effects from PrEP are rare. A small percentage of people taking oral PrEP experience side effects like headache, diarrhea, nausea, headache, fatigue, and stomach pain, but these side effects are typically mild and usually go away after the initial "start-up" period of several weeks.¹⁶ The most common side effects of injectable PrEP are transient pain and swelling at the injection site and are more likely with the first few injections. Patients should be encouraged to inform their healthcare provider of any side effects so the provider can ensure appropriate monitoring and initiate a discussion about management options. In rare instances people may choose to discontinue PrEP due to side effects. In these cases, discussing other HIV prevention strategies is advised.

Most PrEP users do not experience any adverse effects.

There are few significant drug interactions with PrEP medications. For more information, see the tables of oral PrEP medication drug interactions and cabotegravir PrEP drug interactions in

Appendix E at the end of this guide, reproduced from <u>CDC's PrEP Clinical Practice Guidelines</u>. The University of Liverpool's online <u>HIV drug interactions checker</u> is also a useful tool.

¹⁵ The <u>IPERGAY</u> trial evaluated on-demand PrEP in men who have sex with men in Canada and France and found that it reduced the risk of HIV infection by 86%. The <u>PREVENIR</u> study found that on-demand PrEP was equally effective at preventing HIV infection in MSM when compared to daily PrEP. A <u>pharmacologic study</u> found that TDF/FTC reaches target levels in colorectal tissue in 98% of participants 24 hours after an initial two-pill dose and in 81% of participants 2 hours after an initial two-pill dose.

¹⁶ For more information on side effects, see: <u>https://prepdaily.org/what-are-the-side-effects-of-prep/</u>.

PrEP and hormone use

Oral and injectable PrEP can be safely and effectively used alongside hormone therapy. Studies have demonstrated that oral PrEP does not change blood levels of hormones. Use of feminizing hormones (estrogens and spironolactone) has been shown to lower blood and rectal levels of the PrEP medication tenofovir – however, PrEP levels remain above the necessary threshold to confer protection when PrEP is taken daily.¹⁷ On-demand PrEP is not recommended for patients concurrently on hormone therapy. There are no known interactions or concerns with use of long-acting injectable PrEP alongside hormone therapy. Gender-affirming use of testosterone has not been noted to have any significant interaction with PrEP medications. In-depth information about PrEP and gender-affirming hormone therapy is available in the National HIV PrEP Curriculum quick reference section <u>HIV PrEP for transgender and gender-diverse people</u>.

PrEP and contraceptive use

Oral and injectable PrEP can be safely and effectively used alongside all contraceptive methods. Further information about PrEP and hormonal contraceptive use is available in the National HIV PrEP Curriculum quick reference section on <u>HIV PrEP for cisgender women and pregnant</u> <u>persons</u>.

PrEP and conception, pregnancy, and breast/chestfeeding

Periconception and pregnancy are both associated with an increased risk of HIV acquisition. TDF/FTC (Truvada[®] or generic) can be safely and effectively used in patients who are trying to conceive, pregnant, or breast/chestfeeding. Limited data exist about the use of injectable PrEP in conception, pregnancy, and breast/chestfeeding. Federally approved clinical practice guidelines for the use of PrEP in conception, pregnancy, and postpartum are available at <u>clinicalinfo.hiv.gov</u>. Further information is available in the National HIV PrEP Curriculum quick reference section on <u>HIV PrEP for cisgender women and pregnant persons</u>.

For additional guidance about PrEP for transgender patients, patients trying to conceive, pregnant and breast/chestfeeding patients, and drug interactions with PrEP, consult the <u>CDC</u> <u>Clinical Practice Guidelines on PrEP for the Prevention of HIV Infection</u>.

Opportunities for PrEP

Educating patients about PrEP builds awareness of this highly effective HIV prevention tool and can help to reduce stigma and normalize PrEP use and conversations about HIV.

An STI diagnosis is a key opportunity to discuss and start PrEP for HIV prevention and to plan for regular, routine HIV and STI testing. In 2022, 23.8% of people

An STI diagnosis is a key opportunity to offer PrEP for HIV prevention.

diagnosed with HIV in Oregon had a prior STI diagnosis (syphilis, gonorrhea, and/or chlamydia) within the preceding 24 months. <u>Extragenital testing</u> for gonorrhea and chlamydia is

¹⁷ Learn more about interactions between PrEP and hormone therapy at <u>https://www.aidsmap.com/about-hiv/interactions-between-prep-and-gender-affirming-hormone-therapy</u>

recommended for patients who have oral and/or anal sex to avoid missing cases of rectal and/or pharyngeal STI. This requires that a detailed sexual history be taken to identify anatomic sites of exposure for screening.

All patients should be educated about PrEP as a part of comprehensive sexual healthcare assessment and counseling. Patients seeking information or services related to injection or non-injection drug use, contraception, or gender-affirming care, as well as those transitioning out of carceral settings, may also benefit from learning about PrEP as an option available to them.

Patients may avoid seeking out PrEP or hesitate to consider PrEP due to concerns about prohibitive costs. Communicating that PrEP is fully covered by most insurance plans and that patient assistance programs are available to offset costs – as well as connecting patients to benefits coordinators or service navigators – is an essential part of PrEP education.¹⁸

Transitioning from PEP to PrEP

HIV Post-Exposure Prophylaxis (PEP) is an emergency medication used to prevent HIV infection after a possible HIV exposure. It is a 28-day course of daily oral medication and <u>must be started within 72 hours</u> of the possible HIV exposure. PEP is sometimes categorized as oPEP (Occupational PEP) and nPEP (Non-Occupational PEP) to differentiate the type of HIV exposure involved.

Patients prescribed PEP who have an ongoing possibility of exposure to HIV may transition directly from PEP to PrEP without interruption once they have completed the 28-day course of PEP. Clinical guidelines for managing the transition from PEP to PrEP are available in Section 9 of <u>CDC's Clinical Providers' Supplement on PrEP</u>.

Ancillary clinical services to accompany PrEP

Routine HIV testing

HIV testing is required to confirm that patients do not have preexisting HIV infection when they start taking PrEP. Routine HIV testing is also required for continuation on oral or injectable PrEP (see schedules in the tables below). CDC guidelines released in 2021 recommend testing for HIV with a 4th generation antigen-antibody HIV test plus an HIV RNA test at each follow-up visit. However, in practice the HIV RNA test is typically only used for patients on injectable PrEP due to the high cost of HIV RNA testing and potential delays in seroconversion while on cabotegravir. The inability to include an HIV RNA test as part of monitoring should not prohibit the use of oral PrEP.¹⁹

PEP Q

Post-exposure prophylaxis: medication taken by individuals who are HIV negative after a possible HIV exposure to reduce the risk of acquiring HIV.

¹⁸ See the "PrEP coverage and payment assistance" section for more information.

¹⁹ National HIV PrEP Curriculum, Follow up Monitoring on PrEP

There are additional considerations for HIV testing among patients who have used oral PrEP or PEP in the past 3 months and patients who have received injectable PrEP in the past 12 months. Consult Figure 4b in <u>CDC's Clinical Practice Guideline on PrEP</u>, also in Appendix B at the end of this document, for guidance on determining HIV status for PrEP provision to patients with recent or ongoing antiretroviral prophylaxis use.

Baseline assessment for acute HIV infection or indication for HIV PEP

In addition to routine HIV testing, patients who want to start using PrEP should be assessed for possible acute HIV infection. The presence of any clinical manifestations suggesting acute HIV infection should delay PrEP initiation until a thorough laboratory evaluation for acute HIV infection has confirmed that the patient does not have HIV. See Figure 1 at <u>National HIV PrEP</u> <u>Curriculum, Baseline Evaluation and Starting HIV PrEP</u>, also in Appendix C at the end of this guide, for the most common clinical signs and symptoms of acute HIV infection.

Patients who have had a possible HIV exposure in the past 72 hours should be provided with PEP immediately and evaluated for later transition to PrEP. All Oregon hospitals are required to be equipped to dispense a minimum 5-day starter supply of PEP to patients who need it. Patient factsheets about PEP are available in <u>English</u> and in <u>Spanish</u>.

Other sexual and reproductive health services

According to CDC Guidelines, PrEP should be considered "part of a comprehensive prevention plan that includes a discussion about using PrEP as prescribed, condom use, other sexually transmitted infections (STIs), and other risk reduction methods."²⁰ PrEP does not provide protection against other sexually transmitted infections (STIs) and should therefore be paired

PrEP should be part of a comprehensive prevention plan.

with STI prevention tools such as routine STI testing, barrier methods, and DoxyPEP.²¹ Patients who wish to avoid pregnancy should also receive counseling about contraceptive method options.

Patients taking PrEP may also benefit from DoxyPEP. Doxycycline post-exposure prophylaxis (DoxyPEP) is the use of a single 200mg dose of doxycycline after a possible sexual exposure for bacterial STI prevention. DoxyPEP has been shown to reduce the risk of gonorrhea, chlamydia, and syphilis by 65% when taken 24-72 hours after condomless oral or anal sex.²² See <u>CDC's</u> <u>Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually</u> <u>Transmitted Infection Prevention</u> (June 2024) for detailed recommendations on offering and prescribing DoxyPEP.

²⁰ <u>https://www.cdc.gov/hiv/clinicians/prevention/prescribe-prep.html</u>

²¹ CDC released guidelines in June 2024 for the use of doxycycline post-exposure prophylaxis (DoxyPEP) for bacterial STI prevention.

²² <u>https://www.natap.org/2023/HIV/nejmoa2211934.pdf</u>

Current evidence for DoxyPEP supports its use among people assigned male at birth who have oral and/or anal sex with people with a penis; there is insufficient evidence to recommend DoxyPEP to people who primarily have receptive vaginal/front hole sex. DoxyPEP may be effective for all people who have oral and anal sex with people with a penis, regardless of gender identity and sex assigned at birth. Providers should use shared patient-provider decision-making to help a patient determine if DoxyPEP is right for them. The Oregon Health Authority recommends including DoxyPEP as part of comprehensive sexual healthcare.

DoxyPEP Doxycycline post-exposure prophylaxis: a single dose of doxycycline taken after a possible exposure to reduce the risk of acquiring a bacterial STI.

Timeline of ancillary clinical services to accompany PrEP initiation, continuation, and discontinuation

The tables on the following pages list ancillary services and testing that accompany oral PrEP and injectable PrEP, all of which are typically covered by insurance. If available to you, consider using an electronic medical record (EMR) report to check when patients prescribed PrEP were last seen, when they last received laboratory testing, and when they last refilled their PrEP medications or received their PrEP injection.

Clinicians may call UCSF's <u>National Clinician Consultation Center PrEP Consultation Warmline</u> at 855-448-7737 for a phone consultation. The warmline can provide advice on all aspects of PrEP, including initial and follow-up laboratory evaluations, follow-up and testing protocols, administering medications, addressing adherence issues, transitioning from PEP to PrEP, and more. The warmline is available Monday through Friday, 9am to 8pm EST.

	Timeline of ancillary clinical services to accompany oral PrEP					
	Initiation	Every 3 months	Every 6 months	Every 12 months	At discontinuation	
Assessment	Screening, patient education, identification of contraindications	Medication adherence and behavioral risk reduction support	Medication adherence and behavioral risk reduction support	Medication adherence and behavioral risk reduction support	Behavioral risk reduction support	
Labs	Initial HIV test to confirm HIV negative status ²³ Screen for STIs (syphilis,	4 th generation Ag/Ab with or without HIV RNA Screen for STIs (syphilis,	4 th generation Ag/Ab with or without HIV RNA Screen for STIs (syphilis,	4 th generation Ag/Ab with or without HIV RNA Screen for STIs (syphilis,	4 th generation Ag/Ab test Screen for STIs (syphilis,	
	gonorrhea, chlamydia) based on anatomic site of exposure	gonorrhea, chlamydia) based on anatomic site of exposure	gonorrhea, chlamydia) based on anatomic site of exposure	gonorrhea, chlamydia) based on anatomic site of exposure	gonorrhea, chlamydia) based on anatomic site of exposure	
	Screen for pregnancy in people who could be pregnant	Screen for pregnancy in people who could be pregnant	Screen for pregnancy in people who could be pregnant	Screen for pregnancy in people who could be pregnant		
	Assess baseline renal function		Assess renal function if patient is aged ≥50 or had an eCrCl<90 ml/min at PrEP initiation	Assess renal function	Assess renal function	
	Hepatitis B screening			Llonatitic C corooning if		
	Hepatitis C screening if indicated			Hepatitis C screening if indicated		
	Assess triglyceride and cholesterol levels for patients starting TAF/FTC			Assess triglyceride and cholesterol levels for patients on TAF/FTC		
Vaccines	Offer hepatitis A and B, HPV and Mpox vaccines as indicated					
Other Prevention & Harm Reduction	 If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment services 	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment services	 If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment services 	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment services	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment services	

²³ If no oral PrEP or PEP in the past 3 months and no injectable PrEP in the last 12 months, screen for HIV with a 4th generation lab-based antigen-antibody test (preferred) or blood rapid test. If oral PrEP or PEP in the past 3 months or injectable PrEP in the last 12 months, use a 4th antigen-antibody test and an HIV RNA test. Consult Figures 4a and 4b in the <u>CDC's Clinical Practice Guideline on PrEP</u>, also at the end of this document in Appendix B, for guidance on determining HIV status for PrEP provision to patients without recent antiretroviral prophylaxis use (Figure 4a) and with recent or ongoing antiretroviral prophylaxis use (Figure 4b).

Timeline of ancillary clinical services to accompany injectable PrEP					
	Initiation	1 month after first injection	Every 2 months (beginning 2 months after first injection)	Every 12 months	At discontinuation
Assessment	Screening, patient education, identification of contraindications, consider optional oral lead-in ²⁴ with Vocabria®		Behavioral risk reduction support	Behavioral risk reduction support, assess desire to continue injectable PrEP	Behavioral risk reduction support
Cabotegravir Administration ²⁵	Initiation injection #1	Initiation injection #2	Continuation injection	Continuation injection	
Labs	Initial HIV test to confirm HIV negative status ²⁶	Test for HIV with a 4 th generation Ag/Ab test and HIV RNA	Test for HIV with a 4 th generation Ag/Ab test and HIV RNA	Test for HIV with a 4 th generation Ag/Ab test and HIV RNA	Test for HIV with a 4 th generation Ag/Ab test and HIV RNA
	Screen for STIs (syphilis, gonorrhea, chlamydia) based on anatomic site of exposure		Screen for STIs (syphilis, gonorrhea, chlamydia) based on anatomic site of exposure	Screen for STIs (syphilis, gonorrhea, chlamydia) based on anatomic site of exposure	Screen for STIs (syphilis, gonorrhea, chlamydia) based on anatomic site of exposure
	Screen for pregnancy in people who could be pregnant		Screen for pregnancy in people who could be pregnant	Screen for pregnancy in people who could be pregnant	
	Hepatitis C screening if indicated			Hepatitis C screening if indicated	
Vaccines	Offer hepatitis A and B, HPV and Mpox vaccines as indicated				
Other Prevention & Harm Reduction	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment	If indicated, offer: Contraceptives DoxyPEP Sterile syringe access Drug treatment

²⁴ If oral lead-in is used, the first injection should be administered on the last day of oral lead-in or within 3 days thereafter.

²⁵ For oral bridge dosing and restarting after missed injections, see the National HIV PrEP Curriculum quick reference section on <u>Follow-Up Care and Monitoring on HIV PrEP</u>. ²⁶ If no oral PrEP or PEP in the past 3 months and no injectable PrEP in the last 12 months, screen for HIV with a 4th generation lab-based antigen-antibody test (preferred) or blood rapid test. If oral PrEP or PEP in the past 3 months or injectable PrEP in the last 12 months, use a 4th antigen-antibody test and an HIV RNA test. Consult Figures 4a and 4b in the <u>CDC's Clinical Practice Guideline on PrEP</u>, also at the end of this document in Appendix B, for guidance on determining HIV status for PrEP provision to patients without recent antiretroviral prophylaxis use (Figure 4a) and with recent or ongoing antiretroviral prophylaxis use (Figure 4b).

Pharmacy prescribing of PrEP/PEP

Oregon pharmacists can play a key role in ensuring people have access to PrEP, thanks to legislation passed in 2017²⁷ and 2021²⁸ and Oregon Board of Pharmacy (OBOP) approval of PrEP and PEP prescribing by pharmacists who complete continuing education on HIV prevention medications.²⁹

 Pharmacists may prescribe and dispense PrEP, PEP and DoxyPEP in accordance with OBOP protocols, available on the <u>Oregon Board of</u> Pharmacy website and linked in the "Pharmacist-driven PrEP is a safe, innovative strategy for PrEP delivery that is poised to increase PrEP access, particularly in more rural areas of Oregon where the closest PrEP provider is more than a 60-minute drive in one direction." -Dr. Tim Menza, former Medical Director for Oregon Health Authority HIV/STD/TB Section

resources section of this guide. The OBOP PrEP protocol provides guidance on oral PrEP (Truvada[®] and Descovy[®]) only and does not currently include guidance on long-acting injectable PrEP (Apretude[®]).

- Pharmacists may perform 4th generation antigen-antibody point of care HIV tests and may order and receive other screening tests needed for PrEP prescribing.
- Pharmacists may prescribe a 30-day supply of PrEP based solely on a negative HIV test result and may prescribe up to a 90-day supply of PrEP with all required labs.
- Pharmacists may provide ongoing management of PrEP.
- Pharmacists may prescribe PrEP in person or via electronic means using an audiovisual communication system that prevents the unauthorized disclosure of protected health information.
- Insurers must reimburse pharmacists for evaluating patients for PrEP and PEP at the same rate as any other provider. This provides a critical financial incentive to pharmacists to offer PrEP and PEP. In addition, insurers must cover at least one form of PrEP without prior authorization, regardless of whether the pharmacist is in-network. Some providers, such as Kaiser Permanente, are exempt from this prohibition on network restrictions.

OBOP requires that pharmacists complete "a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma informed

²⁷ HB 2397, passed in 2017, granted the Oregon Board of Pharmacy the authority to allow pharmacists licensed in Oregon to prescribe, dispense, and administer board-approved drugs and devices in alignment with a standard protocol.

²⁸ HB 2958, passed in 2021, requires insurers to reimburse pharmacists for prescribing PrEP and PEP at the same rate they would any other health care provider. It also requires insurers to cover at least one form of PrEP without prior authorization and regardless of whether the pharmacist is in-network.

²⁹ https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/HIVPREVENTION/Pages/preppep.aspx#providers

care." It is up to pharmacists to determine if a training program meets these criteria prior to participating. See the <u>Oregon Health Authority's factsheet on PrEP/PEP Prescribing Training for</u> <u>Oregon Pharmacists</u> for a list of approved pharmacist trainings and related resources.

Prior to prescribing PrEP, a pharmacist must verify all the required laboratory tests for PrEP initiation or ongoing management have been completed and are negative or within range. A negative HIV test must be completed within a 7-day range prior to prescribing. Community pharmacies must have a CLIA waiver to perform CLIA waived 4th generation antigen-antibody point of care HIV tests on-site. If only a negative HIV test result is available, the pharmacist can still prescribe a 30-day supply of PrEP; however, the patient must complete the necessary labs within 30 days and bring in the results to the pharmacist. The <u>Oregon Board of Pharmacy PrEP</u> <u>Protocol</u> stipulates the required tests and their timelines.

PrEP availability and access

Outreach navigation services

Outreach navigation services are available in Spanish and English and include:

- PrEP education and counseling
- Peer support and advocacy
- Follow-ups and check-ins about PrEP
- Connections to PrEP providers
- Help with health insurance access or payment assistance options

Outreach navigation providers serve Oregonians based on their region of residence:

Counties	Navigation Contact
Portland Metropolitan Area:	Cascade AIDS Project
Clackamas, Columbia, Multnomah, Washington, and Yamhill	
Eastern Oregon:	Eastern Oregon Center
Baker, Gilliam, Grant, Harney, Hood River, Malheur, Morrow,	for Independent Living
Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler	
Willamette Valley, Southern Oregon, and the Oregon Coast:	HIV Alliance
Benton, Clatsop, Coos, Crook, Curry, Deschutes, Douglas, Jackson,	
Jefferson, Josephine, Klamath, Lake, Lane, Lincoln, Linn, Marion,	
Polk, and Tillamook	

PrEP provider directory

Any health care provider licensed to write prescriptions can prescribe PrEP. In Oregon, that includes MDs, NPs, DOs, PAs, NDs, and some specially trained pharmacists.

Outreach navigation services to assist with PrEP access are available in all 36 Oregon counties. Services are free and available to anyone. There are currently over 430 Oregon providers listed in the Oregon PrEP Provider Directory. The Oregon AIDS Education & Training Center (ORAETC) hosts a directory of PrEP providers in Oregon and SW Washington, including Spanish-speaking providers, providers offering TelePrEP (virtual PrEP services), and

pharmacist providers at: <u>https://www.oraetc.org/prep-provider-list</u>. Inclusion in this directory indicates that a provider is willing to discuss and provide PrEP to patients – however, the directory is not an exhaustive list of all providers who can and do provide PrEP.

PrEP coverage and payment assistance

Statutory and regulatory background

Daily oral PrEP has the highest evidence-based rating recommendation, a "Grade A," from the U.S. Preventive Services Task Force (USPSTF). The recommendation covers adolescents, adults, and pregnant people. Under the Affordable Care Act (ACA), most private health plans³⁰ and all Medicaid expansion programs must cover all USPSTF Grade A recommended services free of charge. This means plans must provide the following PrEP services for free, without cost-sharing, deductible payments, or copays:

- Daily oral PrEP medication
- PrEP-related office visits (initial and quarterly)
- PrEP-related adherence and STI counseling visits
- PrEP-related labs, including STI testing

Factsheets about the PrEP Grade A recommendation are available in English and in Spanish.

Insurance plans and PrEP coverage

With the 2019 USPSTF Grade A recommendation and the CMS guidance in 2020, plans and insurers cannot use reasonable medical management techniques to restrict the frequency of these services if the frequency is specified in the USPSTF recommendation. That means prior authorization or other "reasonable" management techniques cannot be used. However, plans

³⁰ Nearly all private plans, including employer plans and those offering coverage through ACA marketplaces, are required to provide PrEP services free of charge. The Affordable Care Act (ACA) exempts certain health plans that were in effect when the law was passed, referred to as grandfathered plans, from some standards in the law, including the requirement to cover preventive services without cost sharing, have an external appeals process, or comply with the new benefit and rating provisions in the small group market. In 2019, 22% of firms offering health benefits offered at least one grandfathered health plan, and 13% of covered workers were enrolled in a grandfathered plan. <u>https://www.kff.org/report-section/ehbs-2019-section-13-grandfathered-health-plans/</u>. For more information on insurance plans and impact of the ACA see: <u>https://www.kff.org/report-section/ehbs-2019-section-13-grandfathered-health-plans/</u>, https://www.associationhealthplans.com/group-health/what-is-erisa-health-insurance/

and insurers can use reasonable medical management techniques with respect to PrEP coverage in some circumstances.

Plans and insurers can, for instance, opt to cover only the generic version of PrEP without cost sharing while requiring cost sharing for branded versions (e.g., Truvada[®]). This would encourage use of the generic drug over more expensive branded drugs. However, plans and insurers that do so must have an accommodations process to waive cost sharing when a patient cannot use the generic drug for medical reasons.

Plans and insurers must also have an easily accessible, transparent, and expedient exceptions process for the patient or provider to request a different drug. In the context of PrEP, this process should enable "same day start" (access to PrEP medication on the same day that a person receives a negative HIV test or decides to start taking PrEP).

If a patient is wrongfully charged deductibles and/or cost sharing to access PrEP services, the patient or provider may file a complaint about an uncompliant health plan with the insurance plan regulator. Consult <u>NASTAD's PrEP Cost Sharing Complaint Template</u> for information on how to identify and contact the applicable regulator and for a complaint letter template to use.

Private insurance

Most insurance plans cover PrEP and the necessary screenings, visits, and labs (initial and ongoing) at no cost to the patient. This makes PrEP widely available to more people, including many who formerly found PrEP prohibitive because of high copays and deductibles or exorbitant out-of-pocket costs. Copay assistance is available to those who qualify – see "Patient Assistance Options" below.

Medicaid/Oregon Health Plan (OHP)

Oregonians on Medicaid, locally known as the <u>Oregon Health Plan (OHP</u>), are eligible for PrEP at no cost. PrEP medications and all services related to PrEP are covered at no cost to the enrollee. There will not be a statement sent to the OHP member's home and the services are completely confidential.

Since July 1, 2023, immigration status no longer affects whether someone qualifies for Medicaid/OHP. This means that people of any immigration status who meet income and other criteria will qualify for full OHP benefits, Immigration status does not impact OHP eligibility, and OHP enrollment will not affect immigration status or immigration applications.

including full coverage of PrEP medications and services. In addition, on March 9, 2021, the expanded federal <u>public charge</u> rule was blocked permanently – it is no longer in effect anywhere in the United States. This means that immigrants can safely apply for and receive public health benefits without affecting their immigration status.

Medicare

Starting September 30, 2024, Medicare Part B covers oral and injectable PrEP medications and related services without cost-sharing. This means that Oregonians on Medicare are eligible for PrEP at no cost. To ensure that there will be no out-of-pocket cost for PrEP, the patient should ensure that their healthcare provider and laboratory accept assignment (which means they accept the Medicare-approved amount as full payment for a service) and that their pharmacy can bill Medicare Part B.³¹ More information about Medicare Part B billing and coding for PrEP is available in the CMS Fact Sheet on Medicare Part B Coverage of HIV PrEP.

Patient assistance options for uninsured and underinsured patients

Most health plans cover PrEP services free of charge. However, patients with private health plans that are exempt from the ACA requirement to cover Grade A services may face copays and other cost-sharing requirements. Patients without insurance coverage or financial assistance can expect the following PrEP-related expenses:³²

PrEP Component	Cash Price
Oral PrEP medication, generic TDF/FTC	~\$360 per year
Oral PrEP medication, Truvada [®] or Descovy [®]	~\$22,000 - \$24,000 per year
Injectable PrEP (cabotegravir/Apretude [®])	~\$22,200 per year
	(\$3,700 per 3mL dosing kit)
Laboratory tests	~\$500 - \$1700 per year
	(Varies based on tests indicated such as
	multi-site STI testing or pregnancy screening)
Primary care provider visit	~\$73 - \$179 per visit
	(Initial visit and quarterly visits thereafter)

<u>Generic TDF/FTC is appropriate for most patients and is an extremely cost-effective option at</u> <u>about \$30 per month.</u> There are no copay assistance programs or payment assistance programs available for generic TDF/FTC for PrEP. Patients prescribed the brand-name medications Descovy[®] or Apretude[®] – generally those who are not able to take TDF/FTC and those who strongly prefer injectable PrEP – may experience higher costs for PrEP medications.

For patients facing financial barriers to accessing PrEP, whether they are uninsured or underinsured, there are several financial assistance options outlined in the table on the following page. Income restrictions and maximum award levels may be subject to change and should be confirmed on the linked websites for each program.

³¹ Most pharmacies can bill Medicare Part B, but some smaller pharmacies may not be able to. For assistance finding a pharmacy that can bill Part B, call 1-800-MEDICARE (1-800-633-4227) or 1-877-486-2048 for TTY users. ³² This table was adapted from figure entitled "Cost of PrEP Care, the Patient Perspective" which was included in "Barriers and Opportunities in PrEP Access" presented by Edwin Corbin-Gutierrez, NASTAD Senior Program Advisor, at the May 2024 PrEP Policy Summit in Philadelphia, PA.

Program Name	Assistance Provided	Income Restrictions	Eligible Medications		
Gilead Advancing	Medication payment	500% of the Federal	Truvada®		
Access Patient	assistance for	Poverty Level	Descovy®		
Assistance Program	uninsured patients		20001		
ViiVConnect Patient	Medication payment	500% of the Federal	Apretude®		
Assistance Program	assistance for	Poverty Level	Vocabria®		
<u>Alasistance Program</u>	uninsured patients		Vocabila		
	and some insured				
	patients				
ViiVConnect	Deductible and	No income restrictions	Apretude®		
Apretude [®] Savings	copay assistance for		, pretude		
Program	those with private or				
	employer-sponsored				
	health insurance				
Gilead Advancing	Medication copay	No income restrictions	Truvada®		
Access Copay	assistance for those		Descovy®		
Program	with private or		Descovy		
<u></u>	employer-sponsored				
	health insurance				
Patient Advocate	Medication copay	500% of the Federal	Any PrEP medication		
Foundation Copay	assistance for those	Poverty Level	covered by insurance		
Program	with health				
	insurance				
Good Days	Medication copay	500% of the Federal	Any PrEP medication		
	assistance for those	Poverty Level	covered by insurance		
	with military		,		
	insurance				
Ready, Set, PrEP*	Medication payment	No income restrictions	Truvada®		
	assistance for		Descovy®		
	uninsured patients				
*NOT ACCEPTING NEW ENROLLMENTS – WILL CONTINUE TO SERVE CLIENTS ENROLLED PRIOR TO JULY 31, 2024					

Gilead Advancing Access Patient Assistance Program / Medication Assistance Program

This medication assistance program provides financial assistance to uninsured patients to pay for Truvada[®] or Descovy[®]. It does not cover the cost of clinical visits or labs. The program is available to uninsured individuals, regardless of immigration status. The household income limit for the program is 500% of the <u>Federal Poverty Level</u>. Applicants will be asked to submit further documentation as proof of income. Learn more at <u>www.gileadadvancingaccess.com</u>.

ViiVConnect Patient Assistance Program

This medication assistance program provides Apretude[®] and Vocabria[®] at no cost to qualifying patients. It does not cover the cost of clinical visits or labs. The program is available to individuals who are not eligible for Medicaid and who are either uninsured or who meet certain

other criteria. The household income limit for the program is 500% of the <u>Federal Poverty Level</u>. Learn more at <u>hwww.viivconnect.com</u>.

ViiVConnect Apretude[®] Savings Program

This copay assistance program covers an insured patient's out-of-pocket costs for Apretude[®], up to \$7,850 per year, including medication copays as well as assistance with deductibles and administration fees. It does not cover out-of-pocket costs for clinical visits or labs. It is available to individuals who have commercial health insurance that provides coverage for Apretude[®]. There are no income restrictions to access this program. Learn more at <u>hwww.viivconnect.com</u>.

Gilead Advancing Access Copay Program

This copay assistance program covers an insured patient's out-of-pocket costs for either Truvada[®] or Descovy[®], up to \$7,200 per year. It does not cover out-of-pocket costs for clinical visits or labs. It is available to individuals who have private health plan coverage, including Marketplace plans, and to those with employer-sponsored plans. There are no income restrictions to access this program. Learn more at www.gileadadvancingaccess.com.

The Patient Advocate Foundation Copay Relief

This copay assistance program covers an insured patient's out-of-pocket costs for PrEP medications and services, including co-pays, co-insurance and deductibles, office visits and administration charges, and medical insurance premiums, up to \$5,000 per year. It is available to individuals who have any type of health insurance, and whose income falls below 500% of the <u>Federal Poverty Level</u>, adjusted by the Cost-of-Living Index and the number in the household. Learn more at <u>www.copays.org/funds/hiv-aids-and-prevention</u>.

Good Days

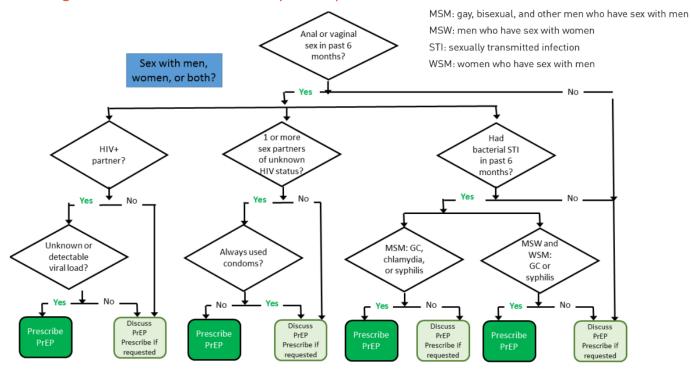
This copay assistance program for patients with military insurance covers out-of-pocket costs for PrEP medication up to \$10,000 per year. It does not cover out-of-pocket costs for clinical visits or labs. It is available to individuals who have military health insurance, and whose income falls below 500% of the <u>Federal Poverty Level</u>, adjusted by the Cost-of-Living Index and the number in the household. Learn more at <u>www.mygooddays.org/diseases-covered/hiv-aids-treatment-and-prevention</u>.

Ready, Set, PrEP (NOT ACCEPTING NEW ENROLLMENTS)

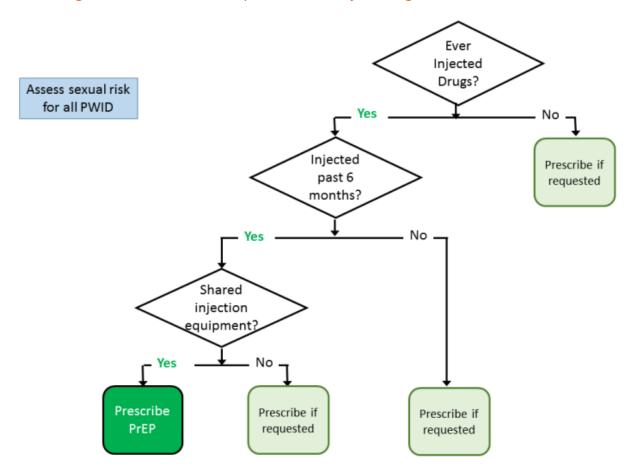
This program, launched nationwide in 2019, stopped accepting new enrollments in July 2024. It continues to serve clients who are already enrolled. Ready, Set, PrEP (RSP) makes Truvada[®] or Descovy[®] available at no cost to those who don't have health insurance coverage for prescription drugs. While RSP covers the cost of medications, it does not cover clinical visits or labs. There are no income restrictions or immigration status requirements to participate in this program. Learn more at <u>www.readysetprep.hiv.gov.</u>

Appendix A: PrEP assessment flows

More information on PrEP assessment is available in <u>CDC's PrEP Clinical Practice Guidelines</u>.



Assessing indications for PrEP in sexually active patients



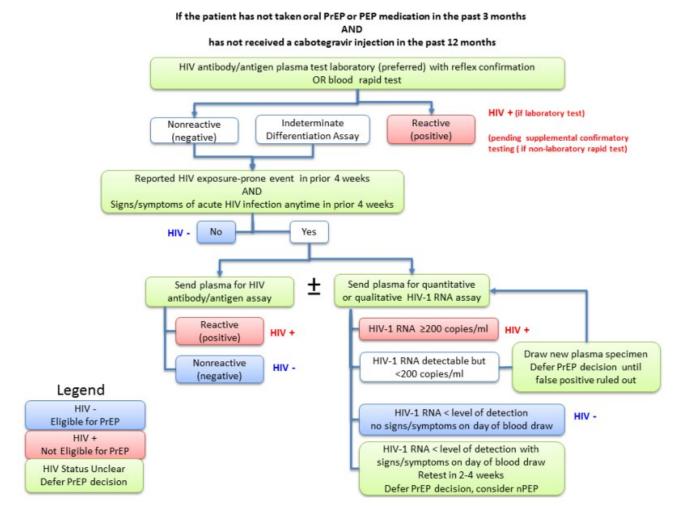
Assessing indications for PrEP in patients who inject drugs

Appendix B: Determination of HIV status for PrEP provision

Clinician determination of HIV status for PrEP provision to persons <u>without</u> recent antiretroviral prophylaxis use

This figure and additional information about laboratory tests and diagnostic procedures are available in <u>CDC's PrEP Clinical Practice Guidelines</u>.

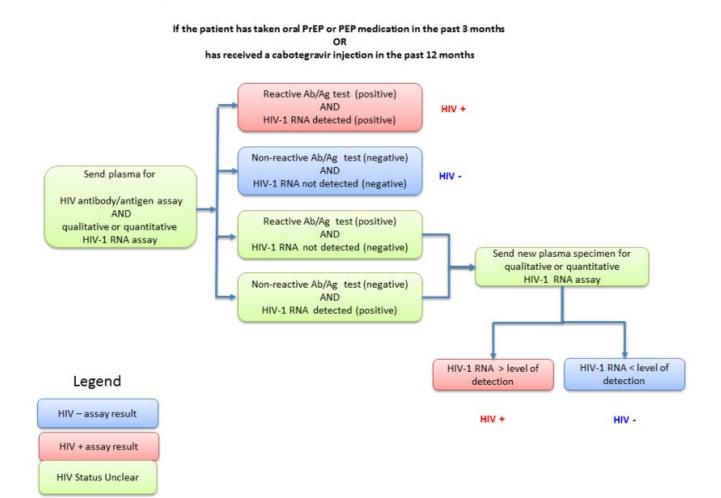
Figure 4a Clinician Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use



Clinician determination of HIV status for PrEP provision to persons with recent or ongoing antiretroviral prophylaxis use

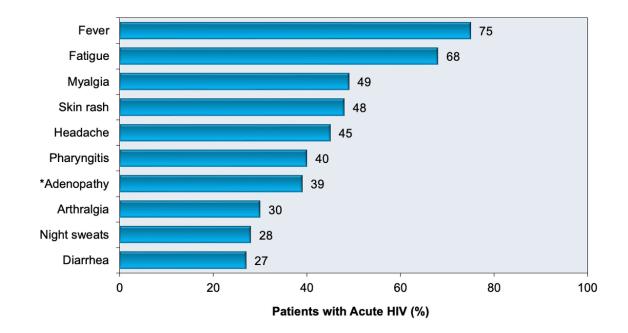
This figure and additional information about laboratory tests and diagnostic procedures are available in <u>CDC's PrEP Clinical Practice Guidelines</u>.

Figure 4b Clinician Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use



Appendix C: Clinical Signs and Symptoms of Acute HIV Infection

This figure³³ and additional information about baseline assessment for HIV PrEP can be found on the <u>National HIV PrEP Curriculum</u>, <u>Baseline Evaluation and Starting HIV PrEP</u> page.



*Adenopathy = cervical adenopathy

³³ Source: Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. Curr Opin HIV AIDS. 2008;3:10-5.

Appendix D: IAS-USA Recommendations for PrEP by population, transmission behavior, and creatinine clearance – quick reference

IAS-USA Recommendations for PrEP by Population, Transmission Behavior, and Creatinine Clearance

Oral TDF/FTC Population, Behavior, and CrCl Oral QD TAF/FTC IM C/				
Population, Behavior, and CrCl	QD	2:1:1		IM CAB
Cisgender men/women				
 Insertive sex (vaginal/anal) 	Yes	Yes	Yes	Yes
 Receptive anal sex 	Yes	Yes	Yes	Yes
 Receptive vaginal sex 	Yes	Insufficient data	Insufficient data	Yes
 Injection drug use 	Yes	Insufficient data	Insufficient data	Insufficient data
Transgender women				
 Insertive sex (vaginal/anal) 	Yes	Yes	Yes	Yes
 Receptive anal sex 	Yes	Yes	Yes	Yes
 Receptive (neo) vaginal sex 	Yes	Insufficient data	Insufficient data	Yes
 Injection drug use 	Yes	Insufficient data	Insufficient data	Insufficient data
Transgender men				
 Receptive anal sex 	Yes	Yes	Yes	Yes
 Receptive vaginal ("front hole") sex 	Yes	Insufficient data	Insufficient data	Yes
 Injection drug use 	Yes	Insufficient data	Insufficient data	Insufficient data
Creatinine clearance	>60	>60	>30	No restrictions
andhi R JAMA 2022				

The full IAS-USA recommendations are available here: <u>https://www.iasusa.org/wp-content/uploads/guidelines/arv/arv_2022.pdf</u>

Appendix E: PrEP drug interactions

Oral PrEP medication drug interactions

Table reproduced from Table 4 of <u>CDC's PrEP Clinical Practice Guidelines.</u>

	TDF	TAF			
Buprenorphine	No significant effect				
	No dosage adjustment necessary				
Methadone	No significant effect				
	No dosage adjustment necessary				
Oral contraceptives	No significant effect				
	No dosage adjustment necessary	/			
Feminizing hormones	Lower tenofovir-diphosphate	No data available			
(spironolactone, estrogens)	rectal tissue levels (unknown if				
	it affects PrEP effectiveness).				
	TDF does not affect hormone				
	levels				
Acyclovir, valacyclovir,	Serum concentrations of these	No data available			
cidofovir, ganciclovir,	drugs and/or TDF may be				
valganciclovir,	increased. Monitor for dose-				
aminoglycosides, high-dose	related renal toxicities				
or multiple NSAIDS or other					
drugs that reduce renal					
function or compete for					
active renal tubular secretion					
Adefovir	Do not co-administer with TDF	No data available			
	Serum concentration of TDF				
	may be increased, monitor for				
	toxicities				
Ledipasvir, sofosbuvir,	Serum concentrations of TDF	No significant effect			
velpatasvir, voxilaprevir	may be increased. Monitor for				
	toxicities				
St John's Wort	No significant effect	Do not co-administer with			
	_	TAF			
		Decrease in TAF			
		concentration possible			
Rifampin	No significant effect	Do not co-administer with			
		TAF unless benefits			
		outweigh risks			
Rifabutin, rifapentine	No significant effect	Do not co-administer with			
		TAF			

Cabotegravir PrEP drug interactions

Table reproduced from Table 6 of <u>CDC's PrEP Clinical Practice Guidelines.</u>

Rifampicin, rifapentine	Do not co-administer with CAB
	Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB
Rifabutin	Co-administer with caution
Hormonal contraceptives	Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB No significant effect
Feminizing hormones (spironolactone, estrogens)	No data yet available
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	Do not co-administer with CAB
	Concern that these anticonvulsants may
	result in significantly reduced exposure to
	protective levels of CAB but strength of
	evidence is weak

Patient handout: frequently asked questions about PrEP access

What if I don't have insurance?

PrEP has become much more affordable since generic options have become available. Most PrEP prescriptions are for the generic version of oral PrEP, which costs around \$30 per month. Community clinics like <u>Planned Parenthood</u> and <u>Federally Qualified Health Centers</u> offer free or low-cost office visits and laboratory tests. You can also contact an <u>outreach navigator</u> for help finding affordable care. Outreach navigators can also help you enroll in the <u>Oregon Health Plan</u> if you are eligible and can help you apply for patient assistance programs if needed.

What if I have insurance, but I'm worried about medication copays and other costs?

Most insurance plans must cover the full cost of PrEP medications and the medical visits and labs associated with PrEP – so your visits and prescriptions should be covered in full, with no copays. This requirement started in 2021, so if you tried to get PrEP before and were faced with large copays or other expenses, try again! If your insurance plan does not cover all of your costs, consider seeking free or low-cost services from a community clinic such as a <u>Federally Qualified Health Center</u> or <u>Planned</u> <u>Parenthood</u> and applying for copay support through a <u>patient assistance program</u>. You can also contact an <u>outreach navigator</u> for help with any insurance questions including determining what your insurance covers. Outreach navigators can also help you apply for patient assistance programs.

What if I'm on gender-affirming hormone therapy?

Daily oral PrEP and injectable PrEP can be safely and effectively used alongside hormone therapy. Studies have shown that PrEP use does not change blood levels of hormones, so it will not interfere with gender-affirming hormone therapy. Some hormones have been noted to slightly reduce blood and rectal levels of the oral PrEP medication tenofovir, but not enough to make a difference: PrEP levels remain at protective levels when oral PrEP is taken daily. On-demand PrEP is not currently recommended for patients on hormone therapy due to a lack of research. You can learn more about research on PrEP and hormone use online at <u>Aidsmap</u> and <u>Poz</u>. Talk to a health provider if you have concerns about using PrEP and hormones.

Will my medical provider judge me if I ask for PrEP?

There are many reasons why someone might want to use PrEP. It's important to find a provider who is knowledgeable about PrEP, or who is supportive and willing to learn about PrEP. You deserve to have a provider you can talk freely with, who you trust, and who makes you feel comfortable. Providers specializing in reproductive health, HIV, and/or LGBTQ care – such as <u>LGBTQ-friendly clinics</u> and <u>Planned Parenthood</u> – are often most informed about PrEP. There are also over 430 providers across Oregon who asked to be listed on the <u>PrEP Provider Directory</u>, indicating that they are open to discussing and providing PrEP. Some of these providers offer telehealth services, so you can meet with them to discuss PrEP virtually.

What if I'm under 18 years old?

In Oregon, minors 15 years of age and older can consent to medical services without parental consent and minors of any age can access family planning and sexual and reproductive health services without parental consent. Oregon providers are allowed – but not required – to inform a parent about a minor's care, diagnosis, or treatment. Talk to your provider or an <u>outreach navigator</u> if you have concerns about information being shared with a parent or guardian.

What if I'm on my parents' insurance and want to keep my PrEP use private?

There are ways to protect your privacy, even if you are on a parent's insurance plan. Most insurance plans send out Explanations of Benefits (EOB) letters, which are summaries of the healthcare services you have received. This letter may be sent to the person who pays for your health insurance plan (the primary account holder). However, Oregon law guarantees you the right to have protected health information sent directly to you instead of to the primary account holder. You can receive this information directly via email, telephone, or a different mailing address. See <u>Oregon's Patient Right to Privacy website</u> for information, including the <u>Request for Confidential Communication form</u>. The Oregon Health Plan (Medicaid/OHP) does not send out EOBs. Always talk to your provider about your confidentiality concerns.

What if I don't currently have legal documentation to reside in the US?

On March 9, 2021, the expanded federal <u>public charge</u> rule was blocked permanently – it is no longer in effect anywhere in the United States. This means that immigrants can safely apply for and receive public health benefits without affecting their immigration status. If you have questions about public charge, consult <u>PIF's Public Charge Community Resources</u> or contact an immigration lawyer. Immigration status does not affect whether someone qualifies for the Oregon Health Plan (Medicaid/OHP). This means that people of any immigration status who meet income and other criteria will qualify for full OHP benefits, including full coverage of PrEP medications and services. Consult the <u>Oregon Health Plan website</u> or an <u>outreach navigator</u> to learn more about OHP enrollment.

What if my insurance company still requires prior authorization for PrEP?

<u>Oregon Health Plan</u> clients will not face prior authorization requirements or copays for PrEP. If your insurance company is still requiring prior authorizations and charging copays, you can appeal to remove these barriers. You can also ask your provider to appeal the insurance plan's policies and practices. Many insurance plans will cover an initial supply of medications until your appeal is resolved. Patient assistance programs can also help cover medication copays. Connect with an <u>outreach</u> navigator or the state insurance commissioner for assistance.

What if I've used PrEP before but stopped taking it – will it be approved again?

Plans and insurers cannot restrict the number of times an individual may start and stop PrEP.

How can I find an outreach navigator to assist me with PrEP access and coverage?

There are three organizations that currently provide free navigation services:

- <u>Cascade AIDS Project</u> serves Clackamas, Columbia, Multnomah, Washington, and Yamhill Counties.
- <u>Eastern Oregon Center for Independent Living</u> serves Baker, Gilliam, Grant, Harney, Hood River, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler Counties.
- <u>HIV Alliance</u> serves Benton, Clatsop, Coos, Crook, Curry, Deschutes, Douglas, Jackson, Jefferson, Josephine, Klamath, Lake, Lane, Lincoln, Linn, Marion, Polk, and Tillamook Counties.

Additional resources for providers and navigators

PrEP basics:

CDC PrEP page HIV.gov PrEP page Oregon AIDS Education & Training Center (AETC) PrEP page Oregon Health Authority PrEP & PEP page NASTAD PrEP/PEP Access Microsite National HIV PrEP Curriculum (including the free app HIV PrEP Tools for Clinicians, which provides support in PrEP evaluation, selection of appropriate HIV PrEP medications, and ordering recommended laboratory tests)

Clinical Guidelines, Consultation, and Mentorship:

<u>CDC Clinical Resources for Clinicians: Clinical Guidance for PrEP</u> <u>CDC Clinical Practice Guidelines on PrEP for the Prevention of HIV Infection</u> <u>CDC Clinical Providers' Supplement on PrEP for the Prevention of HIV Infection</u> <u>CDC's Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for</u> <u>Bacterial Sexually Transmitted Infection Prevention</u> (June 2024) <u>National Clinician Consultation Center PrEP Quick Guide</u> <u>National Clinician Consultation Center PrEP Consultation</u> <u>Oregon AETC Provider Mentorship Program</u>

USPSTF Grade A Recommendation:

PrEP Grade A Recommendation Infographic in <u>English</u> and <u>Spanish</u> <u>US Preventive Services Task Force- recommendation of PrEP</u> <u>O'Neil Law Georgetown: Ensuring Compliance with new Federal USPSTF PrEP Guidance</u>

Pharmacy-prescribed PrEP and PEP:

<u>PrEP/PEP Prescribing Training for Oregon Pharmacists</u> <u>Oregon Board of Pharmacy PrEP Protocol</u> Oregon Board of Pharmacy PEP Protocol

Patient Resources and Assistance:

PrEP Provider List

Outreach Navigation Services:

HIV Alliance

Cascade AIDS Project

Eastern Oregon Center for Independent Living

Financial assistance links:

<u>Gilead Advancing Access Patient Assistance Program / Medication Assistance Program</u> <u>ViiVConnect Patient Assistance Program</u> <u>ViiVConnect Apretude® Savings Program</u> <u>Gilead Advancing Access Copay Program</u> <u>The Patient Advocate Foundation Copay Relief</u> <u>Good Days</u> <u>Ready, Set, PrEP</u>

Billing and Coding:

NASTAD Billing and Coding Guide NASTAD's PrEP Cost Sharing Complaint Template Billing for HIV/STI Services Performed by Public Health Agencies & Their Partners Oregon Medicaid Pharmacy Quick Reference Fact Sheet: Medicare Part B Coverage of HIV PrEP

PrEP Medications:

University of Liverpool <u>HIV drug interactions checker</u> **Provider Information Pages:**

> <u>Truvada[®] Provider Information Page</u> <u>Descovy[®] Provider Information Page</u> Apretude[®] Provider Information Page

HIV.gov Drug Database Listings:

<u>Emtricitabine/Tenofovir Disoproxil (Truvada®)</u> <u>Emtricitabine/Tenofovir Alafenamide (Descovy®)</u> Cabotegravir (Apretude® and Vocabria®)

Long-Acting Injectable PrEP:

NASTAD Long-Acting Injectable PrEP Page FDA Announcement on Injectable PrEP California PTC: Injectable PrEP FAQs – Clinical

Additional Considerations:

Understanding Minor Consent and Confidentiality in Health Care in Oregon Oregon Law on Consent for STI Testing and Treatment of Minors

HIV and STI in Oregon:

HIV in Oregon: The Oregon HIV Epidemiologic Profile 2022 End HIV Oregon Dashboard Sexually Transmitted Infections in Oregon Dashboard Oregon Health Authority: HIV, STD, and Viral Hepatitis End HIV Oregon End HIV Oregon Annual Progress Report, December 2023 AIDSVu Oregon Data

PrEP Research and Development: <u>AVAC.org</u> PrEPWatch.org