What is PrEP?

PrEP stands for Pre-Exposure Prophylaxis. It is a medication regimen used by HIV-negative individuals to prevent them from contracting HIV through sex or injection drug use.

PrEP Eligibility and Common Concerns

PrEP is recommended for all individuals that have a high likelihood of contracting HIV. Individuals may not always feel comfortable discussing their risk-factors; therefore PrEP should also be prescribed to individuals who request it, even without disclosing specific risks.

PrEP is safe and effective for anyone that wants it. Side-effects are generally minimal to non-existent and long-term usage is safe. It is recommended that healthcare providers inform all sexually active adult and adolescent patients about PrEP and prescribe PrEP to anyone who is interested, including people who do not report specific HIV risk-factors.

Different PrEP medication and methods of administration are available to meet patients' needs regarding medication adherence. In addition, there are financial assistance programs to support clients if their insurance is not adequate. An individual being prescribed PrEP is not indicative of increasing future “high-risk” behavior.

Key Messages

- PrEP reaches maximum protection in blood and rectal tissue after approximately 7 days of consistent oral dosing, and in cervicovaginal tissue after about 20 days. For injectable PrEP, maximum protection against HIV is generally achieved around 7 days after the initial injection.
- PrEP does not interfere with hormone therapy or any form of birth control. If someone becomes pregnant, they do not need to stop taking PrEP.
- PrEP does not prevent gonorrhea, chlamydia, syphilis, genital warts, herpes, or hepatitis A, B, or C.
- PrEP does not prevent pregnancy.

PrEP initiation may occur on the same day as the initial clinical evaluation as long as the person tests negative for HIV on an FDA-approved rapid test or lab based blood draw.

PrEP can be prescribed by any practitioner licensed to prescribe medications. There is no requirement that prescribers specialize in HIV or infectious diseases.

PRESCRIBING PrEP

DAILY TRUVADA

or generic equivalent 300/200mg (TDF/FTC)

Recommended for everyone >35 kgs.

99% effective

300/200mg, 1 tab PO daily, 30-day supply with 2 refills for a total supply of not more than 90 days (after negative HIV test)

DAILY DESCOVY

25/200mg (TAF/FTC)

Not recommended for those at risk from receptive vaginal sex

For those who weigh > 35 kgs.

99% effective

25/200mg, 1 tab PO daily, 30-day supply with 2 refills for a total supply of not more than 90 days (after negative HIV test)

APRETUDE

Cabotegravir (CAB)

Recommended for everyone > 35 kgs.

99% effective

Tail period (6-12 months)

600 mg IM (gluteal muscle)

(optional: CAB 30 mg PO daily x 30 days as oral lead-in before 1st injection)

Initial dose, 2nd dose 1 month after 1st dose, then every 2 months

YEZTUGO

Lenacapavir (LEN)

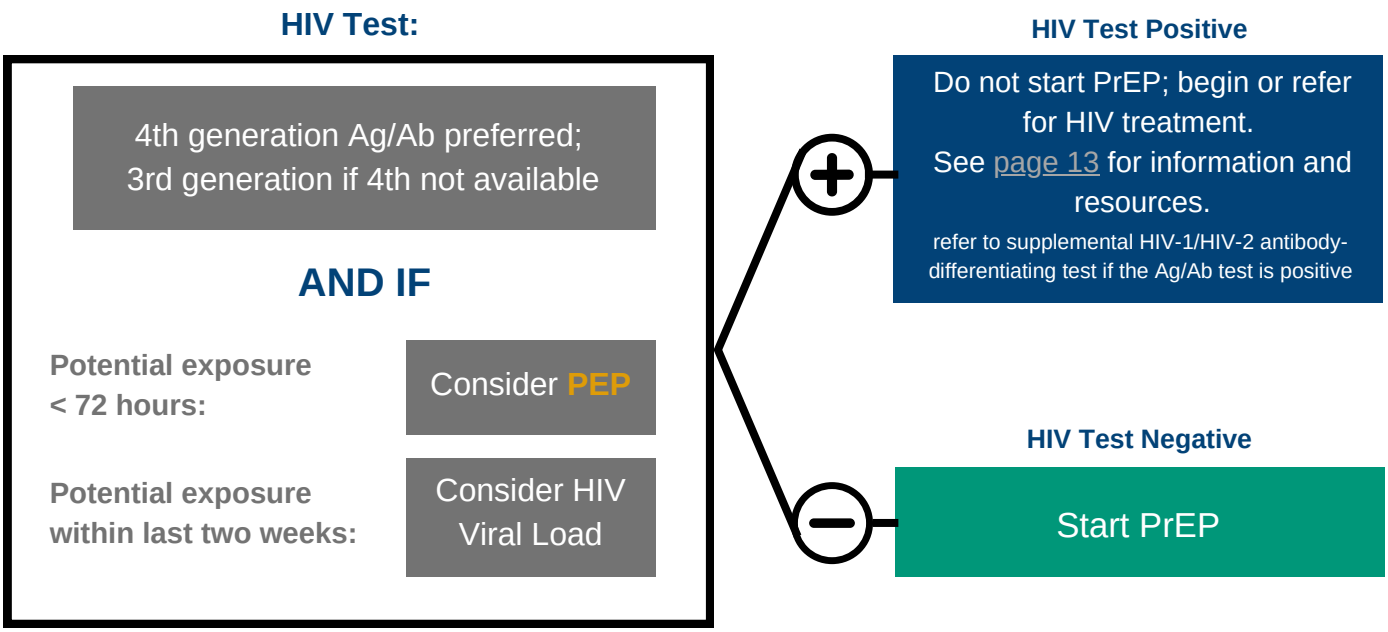
Recommended for everyone > 35 kgs.

99% effective

Tail period (6-12+ months)

Initiation: Day 1: 927 mg SC (2 x 1.5 mL injections) + 600 mg PO (2 x 300 mg tablets) Day 2: 600 mg PO at home
Continuation: 927 mg SC (2 x 1.5 mL injections) every 6 months from last injection

TESTING FOR HIV AND PRESCRIBING PREP



Baseline Assessments and Labs

PrEP prescribed within 7 days of documented negative HIV test

- ☐ **Screen for symptoms of acute HIV:** (fever, fatigue, myalgia/arthralgia, rash, headache, pharyngitis, cervical adenopathy, night sweats, diarrhea) in past 2-4 weeks before PrEP start
- ☐ **HIV test:** Rapid or lab 4th generation Ag/Ab preferred; 3rd generation if 4th not available (plus HIV viral load if concern for acute HIV)
- ☐ **STI testing:** Offer tests according to sites of sexual contact (genital, anal, pharyngeal) for GC/CT and syphilis screen
- ☐ **Oral PrEP:**
  Creatinine (for estimated CrCl)*
  Hepatitis B (HBV) sAb/cAb/Ag**
  Hepatitis C Antibody (MSM, TGW & PWID)**
  Pregnancy test**
  For TAF/FTC: cholesterol and triglycerides
- ☐ **Review medication interactions**

* Serum Creatinine (Creatinine clearance (eCrCl) ⩾60 ml/min for Truvada or ⩾ 30 ml/min for Descovy) - remeasure after 3 months of initiating PrEP.

** Not a contraindication, but follow-up indicated if positive

Follow-up Assessments

Oral PrEP appointments, every 3 months:

- ☐ Screen for symptoms of acute HIV
- ☐ HIV Ag/Ab, HIV RNA
- ☐ Bacterial STI testing for all sexually active patients *every 3-6 months* (see baseline list)
- ☐ Serum Creatine for patients ⩾ 50 or eCrCl < 90 ml/min at PrEP initiation, every 6 months. All other patients, *every 12 months*.
- ☐ Lipid panel- triglyceride and cholesterol (for TAF) and Hep C Ab *every 12 months*
- ☐ Pregnancy test as appropriate

Injectable PrEP appointments:

CAB

- ☐ **1 month:** HIV RNA
- ☐ **Every 2 months:** HIV Ag/Ab and HIV RNA. Pregnancy test as appropriate
- ☐ **Every 4 months:** HIV RNA, STI testing (see baseline list)

LEN

- ☐ HIV test. If using Ag/Ab, do RNA confirmation
- ☐ Hepatitis C Antibody, *every 12 months*

Patient Counseling

Assess Patient Understanding

- Discuss the importance of **daily adherence for maximum effectiveness.**
- If daily adherence is unlikely, consider injectable PrEP.

Monitoring and Follow-up

- **Schedule regular follow-up visits as indicated** to ensure adherence, monitor HIV status, and repeat STI screenings.

Adherence and Support

- Counsel on the importance of **consistent use and strategies to improve adherence** (e.g., reminders, pill boxes). Identify any barriers to adherence and work with patients to address them.

Comprehensive Sexual Health

- **Discuss other aspects of sexual health**, including regular HIV and STI testing, condom use, and overall sexual health. Combining prevention strategies provides the greatest protection from HIV and other STIs.

Side Effects

PrEP is highly effective in preventing HIV. About 1-10% of people may experience mild nausea and fatigue in the first month, but these usually resolve within 3-4 weeks.

Oral

- Assess creatinine clearance (CrCl) before initiating treatment. Monitor CrCl and serum phosphorus in patients at risk.
- Consider assessment of bone mineral density in patients with a history of pathologic fracture or other risk factors for osteoporosis or bone loss.

Injectable

- Hepatotoxicity has been reported in patients receiving cabotegravir. Clinical and laboratory monitoring should be considered.

Potential Risks

- Of the drugs and supplements that interact with **oral** PrEP, non-steroidal anti-inflammatory drugs (NSAIDs) are the most commonly used and should be avoided if possible.
- Many supplements can be combined safely with **oral** PrEP. However taking creatine or protein supplements may affect the results from routine PrEP lab test results.

Which PrEP option/formulation does the patient prefer?

Does the patient have comorbidities/contraindications?

What logistical barriers are there to PrEP adherence?

Taking a Sexual History*

Essential Questions to Ask at Least Annually

Ask every patient the following questions as part of someone's overall medical history. Try to have this conversation, even if your patient seems uncomfortable or you feel awkward

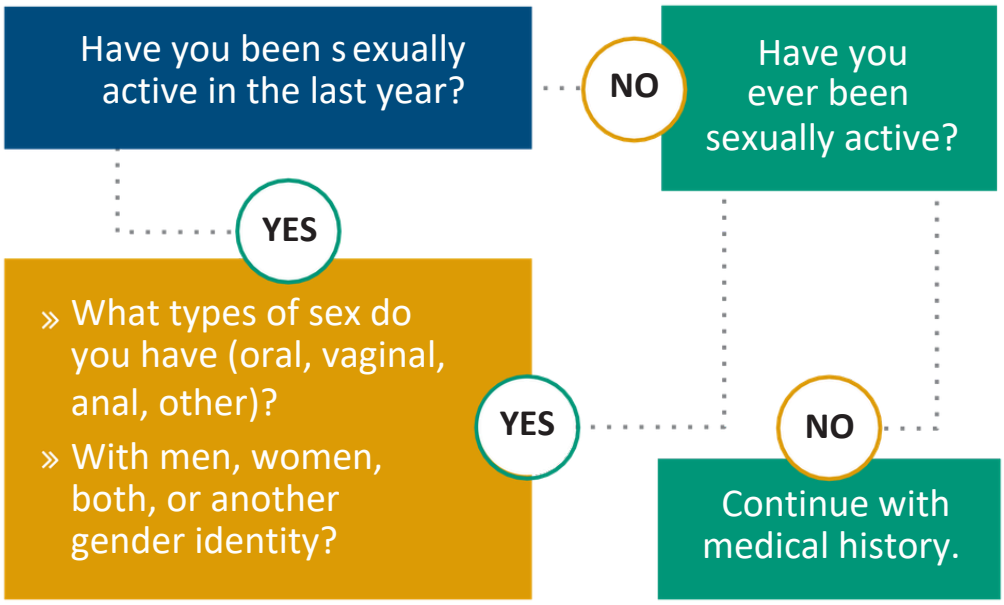
.

Consider using the following script to help you ask these questions and remind your patient that you ask these questions of everyone.

A sexual history should be taken as part of routine health care, as well as when there are symptoms or exam findings suggestive of STIs.

If a partner, relative, or caregiver is in the room, ask that person to step into the waiting room. They can be invited back after the examination.

"I'm going to ask you a few questions about your sexual health. Since sexual health is very important to overall health, I ask all my patients these questions. If you're uncomfortable answering any of these, just let me know, and we'll move on. To begin, what questions or sexual concerns would you like to discuss today?"



Additional Questions to Ask Adults and Adolescents

To better understand your patient's sexual health, determine frequency of STI/HIV screenings, vaccinations and/or medications, and guide counseling, ask questions from CDC's 5 Ps sexual history-taking (Partners, Practices, Past History of STI(s), Protection, and Pregnancy Intention).

The table (on the next page) includes a new sixth P (Plus)—Pleasure, Problems, and Pride—developed by National Coalition for Sexual Health. Questions explore sexual satisfaction, functioning, concerns, and support for one's gender identity and sexual orientation (partly derived from Rubin et al's best practices approach).

Find more provider resources here: Compendium of Sexual & Reproductive Health Resources for Healthcare Providers.

* This page adapted from National Coalition for Sexual Health. Access the full toolkit here: tinyurl.com/bddfhm68

Taking a Sexual History*

Partners	• In the past 12 months, how many sexual partners have you had?
	  ◦ What are the genders of your sexual partners?
	  ◦ Do you or your current partner have other partners?

Practices	• In the past 12 months, what kind of sex have you had? ◦ Vaginal or front hole sex? Oral sex? Anal sex? (Ask whether they give or receive each type of sexual activity.) • How do you meet your partners? • Have you or any of your partners used drugs?
Past History of STIs	• Have you ever had a sexually transmitted infection (or disease)? • If yes, which STI(s)? When did you have it? Were your partners tested and treated too? ◦ Have you had any symptoms that keep coming back? • Do you know your partner(s) HIV status? • Have you ever been tested for HIV? If yes, how long ago was that test? What was the result?
Protection	• What do you do to protect yourself from STIs, including HIV? ◦ When do you use this protection? With which partners? • Have you been vaccinated against HPV? Hepatitis A? Hepatitis B? • Are you aware of PrEP, a medicine that can prevent HIV? Have you ever used it or considered using it?

Pregnancy Intention	• Do you think you would like to have (more) children at some point?
	  ◦ When do you think that might be?
	• How important is it to you to prevent pregnancy (until then)?
	• Are you or your partner using contraception or practicing any form of birth control?
	  ◦ Would you like to talk about ways to prevent pregnancy? Do you need any information on birth control?

Pleasure	Start the conversation with, “It is part of my routine to ask about sexual health, including sexual functioning and pleasure, as part of your visit.”
	• How is your sex life going? What concerns do you have about your sex life?
	  ◦ Is the sex you’re having pleasurable for you? If no, why not?
	  ◦ Are you and your partners on the same page about what’s pleasurable?
	  ◦ Do you and your partners talk openly about sexual desires and boundaries? Are you able to advocate for sexual pleasure in your relationships?
	• If not sexually active:
	  ◦ Would you like to have a sexual relationship or a better sex life?
	  ◦ Is there anything holding you back or getting in your way? (This could lead to a discussion of problems (see “Problems” below) and of other issues such as sexual assault and porn use.)

Problems	• Are you having any difficulties when you have sex (e.g., pain, discomfort, vaginal dryness, lack of arousal, lack of orgasm, lack of erection)? • Are you concerned about your sex drive or the sex drive of your partners (e.g., low or high level of interest in having sex, mismatched sex drives)?
Pride	• What support, if any, do you have from your family and friends about your gender identity? • What support, if any, do you have from your family and friends about your sexual orientation? • Are you experiencing any harassment or violence at home, at work, at school, or in your community —due to your sexual orientation or gender identity?

* This page adapted from National Coalition for Sexual Health. Access the full toolkit here: tinyurl.com/bddfhm68

PrEP Payment Guide

Most insurance plans cover PrEP medication and associated provider visits/ screening tests, but the amount of coverage can vary by individual plan. Insurance companies can change their drug formularies at any time, so it's important to verify medication coverage directly with a plan before enrolling.

For patients without insurance:

MaineCare

MaineCare fully covers all forms of PrEP under part B. This includes the cost of medical visits, lab fees, and prescription costs for PrEP.

To apply, please visit mymaineconnection.gov or call 1-855-797-4357 to speak with an eligibility specialist.

Gilead's Truvada and Descovy Medication Assistance Program

Uninsured patients may be able to receive their Gilead medications (Truvada, Descovy, and Yeztugo) free of charge through Gilead Advancing Access, which lasts for 12 months. There are also options for co-pay assistance.

Beginning 1/31/25, only uninsured individuals assigned female at birth will be eligible for medication assistance for Truvada. To qualify for this exception program, the individual's healthcare provider must submit a letter of medical necessity attesting that the individual was assigned female at birth, based on their clinical judgement, Truvada for PrEP is the most clinically appropriate product for the individual, and the individual is unable to afford the generic alternative. This exception program ends 7/31/25. Co-pay assistance through Gilead remains available to all patients prescribed Truvada.

Please visit gileadadvancingaccess.com or call an Advancing Access program specialist at 1-800-226-2056. Monday–Friday, 9 AM to 8 PM (ET).

ViiV Healthcare's Apretude Medication Assistance Program

ViiVConnect offers a patient assistance program for those who are taking Apretude. It offers their medicine at no cost to those who qualify.

Visit viivpap.org or call a ViiV Healthcare Patient Assistance Program representative at 1-844-588-3288. Monday–Friday, 8 AM–8 PM (ET).

For patients with insurance:

Both Gilead Advancing Access and ViiV Connect offer Co-Pay assistance through their respective patient assistance programs as noted above.

Consider utilizing other resources such as goodrx.com, singlecare.com, and rxsaver.com to bring down out of pocket costs.

For questions regarding PrEP

National Clinician Consultation Center
PrEP Warmline
9 am – 8pm EST,
Monday through Friday
855-448-7737

PrEP207
207-553-7737

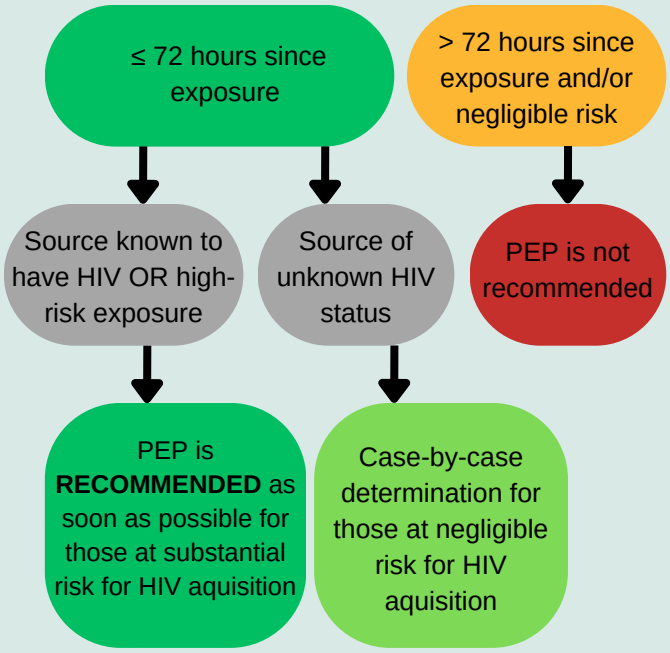
PRESCRIBING PEP

Exposure To HIV Is An Emergency

PEP must begin within 72 hours of exposure. PEP limits HIV's ability to divide and spread.

- **PEP may be up to 80% effective** at reducing the chance of getting HIV when taken as prescribed and as soon as possible after an exposure.
- **Treatment should continue for four weeks**. It involves taking multiple medicines, once or twice a day.

Risk Assessment:



If PEP is not indicated, the patient may still be good candidate for PrEP. Refer for testing and PrEP.

Substantial Risk for HIV Acquisition

Exposure of: vagina, penis, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact

With: blood, semen, vaginal secretions, rectal secretions, breast milk, any body fluid that is visibly contaminated with blood

When: the source is known to have HIV OR the source's HIV status is unknown but the exposure is high-risk (e.g., sexual assault, shared injection equipment, etc.)

Negligible Risk for HIV Acquisition

Exposure of: vagina, penis, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact

With: urine, nasal secretions, saliva, sweat, tears (If visible blood is present, refer to "Substantial Risk" above)

When: regardless of the known or suspected HIV status of the source

Who Should Use PEP?

PEP should be used by anyone who thinks they have been exposed to HIV. People may be exposed to HIV in many ways:

- On the job, such as through an accidental needle stick
- From sexual assault
- During condomless sex
- Sharing needles used for injecting drugs

Side Effects:

The most common side effects from PEP medications are nausea, headaches, fatigue, vomiting, and diarrhea. These can be treated and are not life-threatening.

For Sexual Assault/Abuse Also Consider:

- Empiric antimicrobial regimen
- Emergency contraception
- Postexposure hep B vaccine
- HPV vaccination

PRESCRIBING PEP

Assessments and Labs

- ☐ **HIV test:** Rapid 4th generation Ag/Ab preferred, but if not available, a central blood draw or a rapid Ab test (oral not recommended) should be done. If rapid HIV baseline testing is not available, start PEP immediately and arrange follow-up in 1-2 days for HIV results. *If the baseline rapid test indicates the patient has HIV, do not initiate PEP.*
- ☐ **STI testing:** Offer tests for according to sites of sexual contact for GC/CT and RPR/VDRL or treponemal tests for syphilis.
  - For post-sexual assault patients, STI testing should be considered; empiric treatment should be provided whether or not STI testing is done.
- ☐ **Pregnancy test**, as appropriate
- ☐ **Serum liver enzyme test**
- ☐ **Blood urea nitrogen/creatinine test**
- ☐ **Hepatitis B sAb, cAb, Ag**
- ☐ **Hepatitis C Ab**

Individuals who have experienced repeated HIV exposures outside of a health care setting should consider HIV PrEP. PrEP is an effective prevention option that reduces the likelihood of contracting HIV.

Recommended Therapy

Adults and adolescents (⩾13 years), including pregnant women, see below. Regimens for children and people with reduced renal function are also available. Contact the free National Clinician Consultation Center (NCCC) PEPline at 888-448-4911.

- If the rapid HIV test result is negative (non-reactive), or if a lab-based HIV test is pending, offer PEP along with appropriate treatments such as STI treatment, emergency contraception, hepatitis B prophylaxis, and HPV vaccination.
- Administer the first dose of PEP on-site as soon as the negative rapid HIV test result is obtained or while the non-rapid HIV test is sent for processing.

Preferred Single-Tablet Regimen

BIKTARVY: Bictegravir 50mg + Emtricitabine 200mg + Tenofovir Alafenamide 25mg *PO qd*

Preferred Multi-Tablet Regimen

TIVICAY: Dolutegravir 50mg *PO qd*
PLUS
TRUVADA: Emtricitabine 200mg + TenofovirDF 300mg *PO qd*
OR
DESCOVY: Emtricitabine 200mg + Tenofovir alafenamide 25mg *PO qd*

PRESCRIBING DOXYPEP

Patients taking PrEP may also benefit from DoxyPEP. Doxycycline Post-Exposure Prophylaxis (DoxyPEP) is used to decrease the incidence of acquiring bacterial STIs such as chlamydia, gonorrhea, and syphilis.

Recommend DoxyPEP to patients if they:

- Identify as **gay and bisexual men, other men who have sex with men (MSM), and transgender women (TGW)** who have had a history bacterial STI in the last 12 months.
- Have **frequent condomless sex** (including oral) **with multiple partners** and are at **elevated risk of an STI**.

Effectiveness

- Syphilis and chlamydia infections estimated to be reduced by approximately 80%.
- Gonorrhea infections estimated to be reduced by approximately 50%.

Patient Counseling

DoxyPEP should be offered as part of a comprehensive package of services for reducing risk of exposure to sexually transmitted infections and HIV. All **patients should be offered routine screening** for gonorrhea, chlamydia, syphilis, and HIV (if not already diagnosed with HIV) at baseline and **every 3-6 months.**

Patients should be made aware that **DoxyPEP is not 100% effective against these bacteria and that it does not protect against sexually transmitted viral infections** including herpes simplex virus, human papillomavirus, mpox, and HIV.

Questions remain about potential long-term development of antimicrobial resistance and impacts on the microbiome.

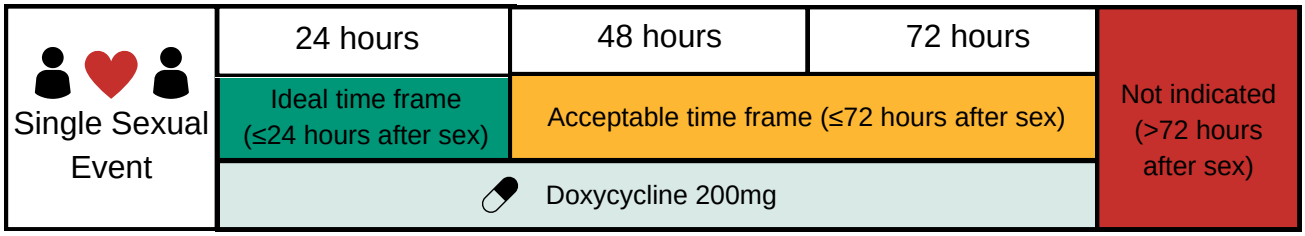
Recommendations

- Take doxycycline with a full glass of water, avoiding lying down for 1 hour after doxycycline ingestion, and consistent use of sun protection when outside.
- Avoid taking doxycycline at the same time as dairy products, antacids, or supplements containing calcium, iron, magnesium, or sodium bicarbonate. Take doxycycline at least 2 hours before or 2 hours after these items.

PRESCRIBING DOXYPEP

With more than one sex event during a 72-hour period, it is important that all exposures are covered by a 200 mg dose of DoxyPEP taken within 72 hours of sexual contact, but the individual should not take more than 200 mg of doxycycline within a 24-hour period.

Dosing Schedule - Single Sexual Event



200 mg of DoxyPEP is ideally taken ⩽24 hours but no later than 72 hours after each episode of condomless sex. Patients should not exceed 200mg in 24 hours.

Baseline Assessments and Labs

DoxyPEP has been demonstrated to be effective among MSM and TGW. DoxyPEP has not been shown to be effective in cis-gender women. The benefit of use in populations beyond those described above is not known.

- ☐ **STI testing:** 3-site gonorrhea and chlamydia NAAT (genital, pharyngeal, rectal) and syphilis screen.
- ☐ Consider HIV test (4th gen Ag/Ab recommended) DoxyPEP is safe to take if living with HIV.
- ☐ Consider complete blood count (CBC), liver function tests (LFTs), and renal function annually.
- ☐ **Pregnancy test,** as appropriate. If positive, then do not prescribe doxycycline. Doxycycline is contraindicated in pregnancy.

Follow-up Assessments

- ☐ Screen for STIs every 3-4 months. If positive, then treat according to CDC STI treatment guidelines.
- ☐ Pregnancy test, as appropriate. If positive, then do not prescribe doxycycline. Doxycycline is contraindicated in pregnancy.

Prescribing DoxyPEP

Doxycycline 200mg can be taken within 72 hours, ideally within 24 hours, of sexual encounter.

No more than 200mg per 24 hours

Available Formulations:

- Doxycycline hyclate delayed release 200mg (1 tab); *OR*
- Doxycycline hyclate or monohydrate immediate release 100mg (2 tabs taken simultaneously).

Consider a 30-day supply to take as needed with 2 refills.

PEP Coverage

Payment for Occupational PEP

Federal law requires covered employers to ensure that all medical evaluations and procedures, vaccines, and PEP medications (7-day starter pack and access to the full 28-day course) are made available to the employee within a reasonable time, at a reasonable location, and at no cost to the employee.

Payment Assistance for Non-Occupational PEP

Care providers should ensure that a patient can acquire the medications needed to continue PEP through 28 days regardless of insurance coverage status. **Most insurance plans cover PEP, including MaineCare.** Options for patients who are uninsured or under-insured include medication assistance programs (MAPs) run by manufacturers and health centers specifically funded to provide PEP at no or low cost.

Clinicians should work with social workers and support staff to enroll patients without alternative means of coverage or payment for PEP in MAPs. These programs often provide one course of PEP. Obtaining future courses may be challenging. Clinicians should consider whether Pre-Exposure Prophylaxis is appropriate for patients who receive PEP from a MAP.

National Clinicians' Post-Exposure Prophylaxis Hotline
888.448.4911 Monday – Friday 8 a.m. – 4 p.m. PT

Payment Methods For PEP Following Sexual Assault

The Maine Victims' Compensation Fund is designed to cover the cost of medical forensic treatment following a sexual assault, including a 3-5 day PEP starter pack.

Additional PEP reimbursements are also available through the fund, but requires that a police report be filed and cooperation with the police investigation.

DoxyPEP Coverage

Payment for DoxyPEP

Most insurance payers will cover DoxyPEP and the clinical visit. For those that are uninsured, online pharmacy coupon programs might help reduce the costs. DoxyPEP is a covered medication for people enrolled in the AIDS Drug Assistance Program (ADAP).

Linking to HIV Care

What if my patient has a positive HIV test on PrEP/PEP?

If a patient on PrEP/PEP tests positive for HIV, it is crucial to address their HIV status promptly and appropriately, as PrEP and PEP are not treatments for HIV.

1. **Confirm the Diagnosis:**
- Repeat HIV Testing: Ensure that the positive HIV test result is confirmed. If necessary, follow-up with an HIV RNA test to confirm the active infection.

2. Immediate Discontinuation of PrEP/PEP
- Discontinue PrEP/PEP as soon as possible once a positive HIV test is confirmed. Continuing PrEP/PEP while the patient is HIV-positive could lead to development of HIV drug resistance.

3. Initiate HIV Treatment (ART):
- Start Antiretroviral Therapy (ART) immediately. HIV-positive individuals should begin a recommended ART regimen promptly, ideally within 7 days of diagnosis.

Resources

Report any positive notifiable conditions to Maine CDC by electronic lab report; by fax to 1-800-293-7534; or by phone to 1-800-821-5821.

National HIV/AIDS Telephone Consultation Service 800-933-3413 Monday - Friday 9 am - 8 pm EST, Voicemail 24/7

Perinatal HIV Hotline 888-448-8765
24 hours a day, 7 days a week

Use the following resources to find an HIV care provider when a referral is needed:

HIV Medicine Association by telephone: 703-299-1215
Ryan White HIV/AIDS Program by telephone: 877-646-4772
HIV.gov

MaineCare Special Benefit Waiver: Eligible individuals with HIV can apply for this waiver to access comprehensive health coverage, including ART and other medical services. Visit the Maine DHHS website or contact a case manager for assistance.

Ryan White Part B: Administers ADAP, and covers HIV meds and insurance for those earning ⩽500% FPL. Requires application with income and residency proof. Annual recertification is required. Extra help (food, dental, rent/utilities) available for those earning ⩽350% FPL with full application. Contact 207-287-3747 or RyanWhitePartB@maine.gov.
No discrimination based on immigration status.

AIDS Drug Assistance Program (ADAP): Refer uninsured or underinsured patients to ADAP for access to HIV medications at no or low cost. Eligibility is based on income and insurance status.