

Prevention Power

Harnessing PrEP, DoxyPEP and Other Tools for STI & HIV Prevention Sarah Weninger, HIV.STI.Hepatitis Prevention Coordinator June 25, 2025



Health & Human Services

Today's Discussion Points

- Review HIV & STI Prevention Strategies
- Understand DoxyPEP Recommendations
- Differentiate HIV PrEP Options
- Highlight Newly Approved HIV PrEP Medication

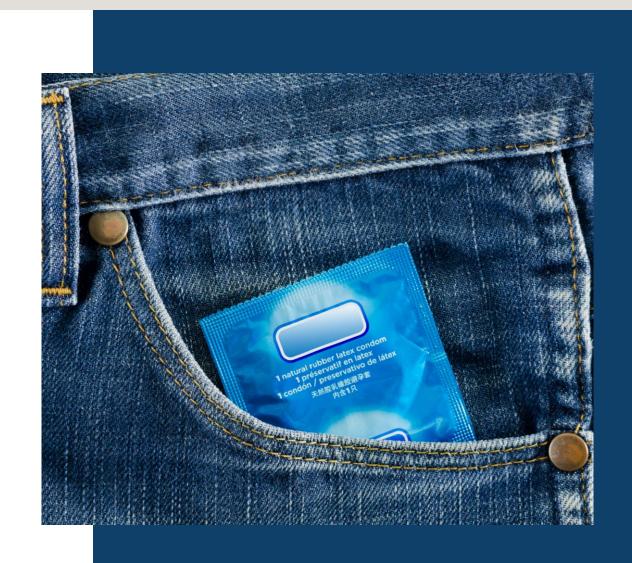




There are Many STI & HIV Prevention Strategies Available

- Abstinence
- Never Sharing Needles
- Consistent, Correct Condom Use
- Hep B & HPV Vaccine
- Pre-Exposure Prophylaxis (PrEP)
- Post-Exposure Prophylaxis (PEP)
- DoxyPEP
- Regular STI & HIV Testing/Treatment





Condom Effectiveness



External Condoms

- Provide Dos and Don'ts
- One Condom: FDA Approved for Anal Intercourse

Internal Condoms

- Can also be used for anal sex
- Don't use an internal and external condom together

Dental Dams

Used for oral sex

CONDOM DOS & DON'TS

DO use a condom every time you have sex.

DO put on a condom before having sex.

DO read the package and check the expiration date.

DO make sure there are no tears or defects.

DO store condoms in a cool, dry place.

DO use latex or polyurethane condoms.

DO use water or silicone-based lubricant to prevent breakage.

DON'T store condoms in your wallet. Heat and friction can damage them.

DON'T use nonoxynol-9 (a spermicide), as this can cause irritation.

DON'T use oil-based products like baby oil, lotion, petroleum jelly, or cooking oil because they will cause the condom to break.

DON'T use more than one condom at a time.

DON'T reuse a condom.











Post-Exposure Prophylaxis (PEP)

- PEP Must Be Started Within 72
 Hours of Exposure to Prevent Infection
- Possible exposures:
 - Unprotected Sex
 - Sharing of Injection Equipment
 - Sexual Assault
 - Occupational Incident





Scientists, including those at the Centers for Disease Control and Prevention (CDC), have studied SSPs for more than 30 years and found that comprehensive SSPs benefit communities.



SSPs save lives by lowering the likelihood of <u>deaths</u> from overdoses.



Providing testing, counseling, and sterile injection supplies helps prevent outbreaks of other diseases. For example, SSPs are associated with a **50% decline** in the risk of HIV transmission.



Users of SSPs were <u>three</u> <u>times more likely</u> to stop injecting drugs.



Law enforcement benefits from reduced risk of needlesticks, **no increase in crime**, and the ability to save lives by preventing overdoses.



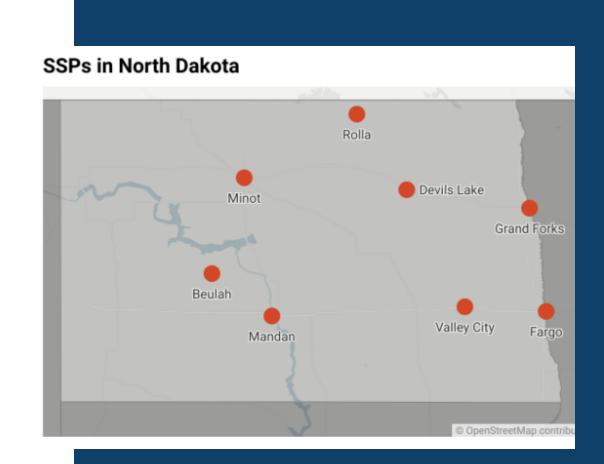
When two similar cities were compared, the one with an SSP had **86% fewer syringes** in places like parks and sidewalks.

Syringe Service Programs

Syringe Service Programs in ND

There are seven authorized SSPs in North Dakota.

- Any Positive Change (APC) Project; Grand Forks, ND
- Harm Reduction Center; Fargo, ND
- Lake Region Syringe Service and Harm Reduction Program; Devils Lake, ND
- Mandan Good Neighbor Project; Mandan, ND
 - Satellite Location: Beulah, ND
- Minot Good Neighbor Project; Minot, ND
- Rolette County Public Health District SSP; Rolla, ND
- The ROPES Project; Valley City, ND





To clean a syringe correctly, you must do all nine steps below:

A. RINSE WITH CLEAN WATER



REPEAT steps 1, 2, and 3 at least once or until water in syringe is clear (no blood).

B. CLEAN WITH PURE BLEACH





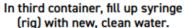
Tap or shake syringe for 30 seconds.



Discard bleach from syringe.

C. RINSE WITH CLEAN WATER







Tap or shake syringe for 30 seconds.



Discard water from syringe.

Because viral hepatitis can survive on surfaces (even if you can't see blood), you should clean cookers with water and bleach.









https://www.cdc.gov/hiv

/resourcelibrary/infoshe

ets/cdc-hiv-consumer-

syringes-2023-508.pdf

info-sheet-cleaning-

DoxyPEP: New Clinical Tool

DoxyPEP

- On June 6, 2024, the CDC issued its official recommendation for the use of doxycycline postexposure prophylaxis (doxyPEP) for the prevention of bacterial STIs!
 - A-I recommendation based on significant effect and several randomly controlled trials
- Safe, effective, inexpensive, and established medication with a new use
 - Targeted intervention to reduce acquisition and transmission of common bacterial STI's

Bachmann LH, Barbee LA, Chan P, et al. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024. MMWR Recomm Rep 2024;73(No. RR-2):1–8. DOI: http://dx.doi.org/10.15585/mmwr.rr7302a1





Morbidity and Mortality Weekly Report (MMWR)

CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024

Recommendations and Reports / June 6, 2024 / 73(2);1–8

Summary

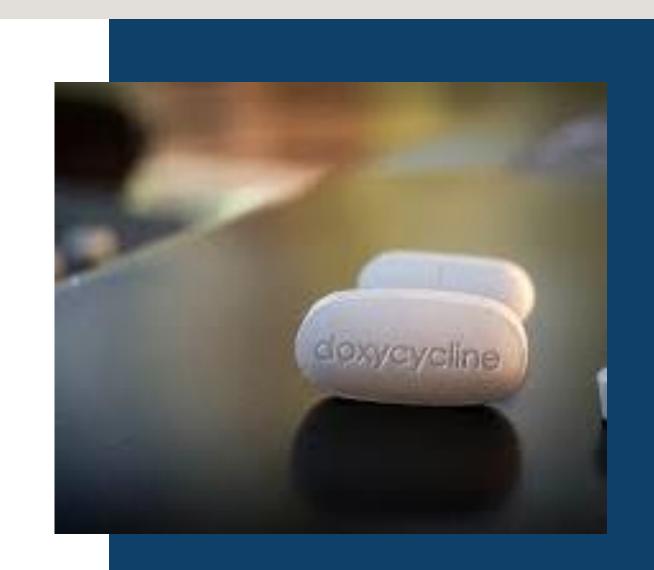
No vaccines and few chemoprophylaxis options exist for the prevention of bacterial sexually transmitted infections (STIs) (specifically syphilis, chlamydia, and gonorrhea). These infections have increased in the United States and disproportionately affect gay, bisexual, and other men who have sex with men (MSM) and transgender women (TGW). In three large randomized controlled trials, 200 mg of doxycycline taken within 72 hours after sex has been shown to reduce syphilis and chlamydia infections by >70% and gonococcal infections by approximately 50%.

This report outlines CDC's recommendation for the use of doxycycline postexposure prophylaxis (doxy PEP), a novel, ongoing, patient-managed biomedical STI prevention strategy for a selected population. CDC recommends that MSM and TGW who have had a bacterial STI (specifically syphilis, chlamydia, or gonorrhea) diagnosed in the past 12 months should receive counseling that doxy PEP can be used as postexposure prophylaxis to prevent these infections. Following shared decision-making with their provider, CDC recommends that providers offer persons in this group a prescription for doxy PEP to be self-administered within 72 hours after having oral, vaginal, or anal sex. The recommended dose of doxy PEP is 200 mg and should not exceed a maximum dose of 200 mg every 24 hours.

Doxy PEP, when offered, should be implemented in the context of a comprehensive sexual health approach, including risk reduction counseling, STI screening and treatment, recommended vaccination and linkage to HIV PrEP, HIV care, or other services as appropriate. Persons who are prescribed doxy PEP should undergo bacterial STI testing at anatomic sites of exposure at baseline and every 3-6 months thereafter. Ongoing peed for doxy PEP should be assessed every 3-6.

DoxyPEP- How it Works

- A patient who qualifies (more on that later) is prescribed 200mg of doxycycline to take after having sex
 - Taken ideally within 24 hrs, but no later than 72 hours after condomless oral, anal, or vaginal sex.
- Can be taken as often as daily, depending on sexual activity,
 - but no more than 200 mg within any 24hr period
- Current indications are for gay, bisexual, and other men who have sex with men (GBMSM) and transwomen



DoxyPEP Effectiveness



SUBSCRIBE

OR RENEW

:

Risk Reduction per Quarter (Doxy-PEP vs Control arm)			
	Chlamydia	Gonorrhea	Syphilis
HIV cohort	74%	57%	77%
PrEP cohort	88%	55%	87%

STI Incidence Reduction



DoxyPEP Rationale



- A single tool / option that can be considered as part of a comprehensive sexual health and wellness program with your patients.
 - Patients should still be tested for STI's every 3 months
 - Works as a fantastic adjunct to PrEP
- Antibiotic Stewardship
 - The same study showed patients taking DoxyPEP took fewer doses of antibiotics than those in the control
 - Greatly reduces usage of Ceftriaxone, preserving one of most important resources
- Bacterial Infections are a conduit for HIV— Harm reduction saves lives







Study Participating population		STI rate or outcome		Relative risk reduction	Absolute risk reduction	
			Doxy-PEP	No doxy-PEP		
IPERGAY* (France, 2015-2016)	232 MSM on HIV PrEP		37.7 per 100 person- years	69.7 per 100 person- years	47%* (15-67%)	32 per 100 person-years
DoxyPEP	501 MSM & TGW with	PWH (n=174)	11.8% per quarter	30.5% per quarter	52% (17-72%)	18.7% per quarter
(Seattle & SF, 2020-2022)	recent bact. STI	PrEP (n=327)	10.7% per quarter	31.9% per quarter	66% (49-77%)	21.2% per quarter
DOXYVAC* (France, 2021-2022)	502 MSM on HIV PrEP with recent bact. STI		5.6 per 100 person- years	35.4 per 100 person- years	84%* (70-92%)	30 per 100 person-years
dPEP (Kenya, 2020- 2022)	449 cis women on HIV PrEP		50 CT/GC infections total	59 CT/GC infections total	12% (P=0.51)	9 total infections at 12 months

^{*}Point estimates are for CT & syphilis only

Molina JM et al, Lancet Infect Dis 2018; Luetkemeyer A et al, NEJM 2023; Molina JM CROI 2023, Stewart J CROI 2023



DoxyPEP Indications

- Current indications are for:
 - Gay, Bi, Men who have sex with men, or trans women

AND

- Have a history of at least one bacterial STI in the last 12 months
- Use clinical judgement and shared decision making for patients who don't meet the above criteria, but you believe could benefit from it
 - Cis/Heterosexual patients in a high-prevalence area
 - Individuals engaged in sex work



Who Should be Offered Doxy PEP?

Broader use

- Meet patient demand
- Below-standard antimicrobial stewardship
- Anti-stigma

Study eligibility Bacterial STI in past year

More restrictive use

- Maximize benefit-risk ratio
- Minimize excess antibiotic use
- More complex to identify candidates

- Without a proactive approach, we risk worsening disparities
- Need to generate evidence to guide the approach (but not wait for it)
- Need to tailor to local epidemiology & resources

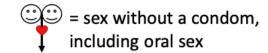


DoxyPEP Dosing

- 200 mg of doxycycline should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex.
- Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24- hour period.
- Either doxycycline hyclate delayed release 200 mg (1 tab) OR doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs taken simultaneously) are acceptable.
- Immediate release may be less expensive than delayed release and should be equivalently bioavailable.
- Study authors have been prescribing 30 doses and tell patients to call if they need more
- For ICD10 diagnosis code, use Z20.2 (Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission).

DoxyPEP Dosing

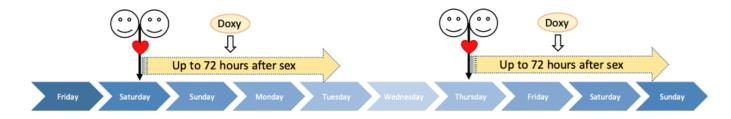
Doxy PEP - How to Take



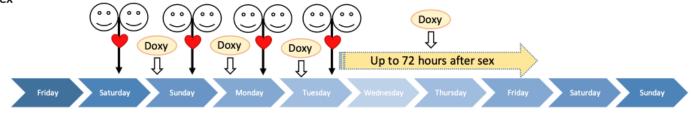
Two 100 mg pills of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sex

Example: Sex on Sat; take dose of doxy by Tues

Example: Sex on Thursday; take dose of doxy by Sunday



Example 2: Daily (or more) sex Sat-Tues; take daily dose of doxy and last dose within 24 hours but not later than 72 hours after last sex



No more than 200 mg every 24 hours



DoxyPEP Monitoring

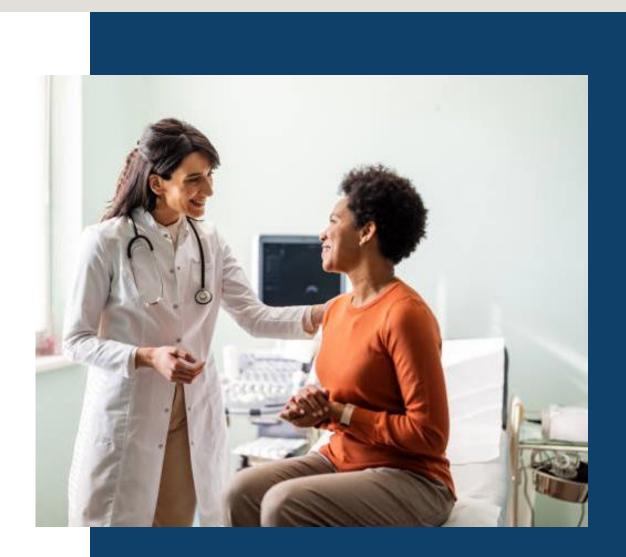
- Consider monitoring LFTs, renal function, and CBC periodically in patients taking doxycycline for a prolonged period as outlined in the drug package insert.
 - Following the same testing algorithm for PrEP patients is an acceptable testing schedule
- Every 3 months, screen for gonorrhea and chlamydia at all anatomic sites of exposure; syphilis and HIV (if not known to be living with HIV).
 - Same as PrEP
- If a patient is diagnosed with an STI while using doxy-PEP, they should be treated according to standard CDC STI treatment guidelines (www.bit.ly/STI guides)
- If a patient utilizing doxy-PEP reports:
 - exposure to a sexual partner with syphilis: epi-treat for syphilis per standard of care.
 - **exposure to a sexual partner with gonorrhea or chlamydia**: consider waiting on epi-treatment until test results are back using shared decision-making with patient.

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DoxyPEP Patient Counseling

- Take doxycycline with fluids and remain upright for 30 minutes after the dose to reduce pill esophagitis. Taking doxycycline with food may increase tolerability.
- Protect against sun sensitivity. Patients should be counseled to wear sunscreen and/or avoid prolonged sun exposure while taking doxycycline.
- Avoid doxycycline during pregnancy. Patients who could get pregnant should receive pregnancy testing and be counseled to stop doxycycline if they become pregnant.
- There is a rare risk of benign intracranial hypertension and other serious side effects.
- The unknown risks of doxy-PEP related to the microbiome and antibiotic resistance.





Doxy PEP: Benefits & Potential Risks

Benefits of **Doxy** PEP

- In Seattle & SF, reduced STI by 65% in MSM and transgender women; median 4 doses of doxy PEP per month
- Could decrease STI rates at population level
- Safe, well tolerated, highly acceptable, high adherence
- Low "number needed to treat" (5 people) for large effect size
- Doxycycline is cheap
- Qualitative data: decreased stigma associated with being diagnosed with and disclosing STI

Potential Risks of Doxy PEP

- Most prevented STIs are asymptomatic. It's not clear if doxy PEP prevents STIrelated morbidity
- Widespread doxy PEP may result in gonorrhea resistance
- Doxy PEP could increase risk of resistance in by stander bacteria like Staph aureus, which can cause severe infections
- Could negatively impact the individual and population-level microbiome
- Goes against trend to use fever antibiotics



Get PrePped!

PrEP (Pre-Exposure Prophylaxis)

- Reduces Risk of Getting HIV
 - From Sex: 99%
 - From Injection Drug Use: 74%
- All Sexually Active Adults & Adolescents Should Be Informed about PrEP
- Oral and Injectable Medications
 - Oral PrEP: Taken Daily
 - Injectable PrEP: First Two Months Monthly Shots, then Bimonthly

WWW.CDC.GOV/HIV/CLINICIANS/PREVENTION/PREP.HTML





HIV PrEP: An Important Component of HIV Elimination

- PrEP, or pre-exposure prophylaxis, is daily medicine that can reduce chance of getting HIV.
- Daily PrEP reduces the risk of getting HIV from sex by more than 99%. Among people who inject drugs, it reduces the risk by more than 70%.
- PrEP should be considered part of a <u>Comprehensive Prevention</u> Plan.



MSM	 HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work
Heterosexual Women and Men	 HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network
Injection Drug Users	 HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)

Updated PrEP Guidelines: December 8, 2021

New Graded Recommendations

- Grade IA. Inform all sexually active adults and adolescents that PrEP can protect them from getting HIV.
- Grade IIIB. Prescribe cabotegravir (CAB) injections as PrEP for sexually active adults. The FDA approved CAB for PrEP in 2021.

US Public Health Service

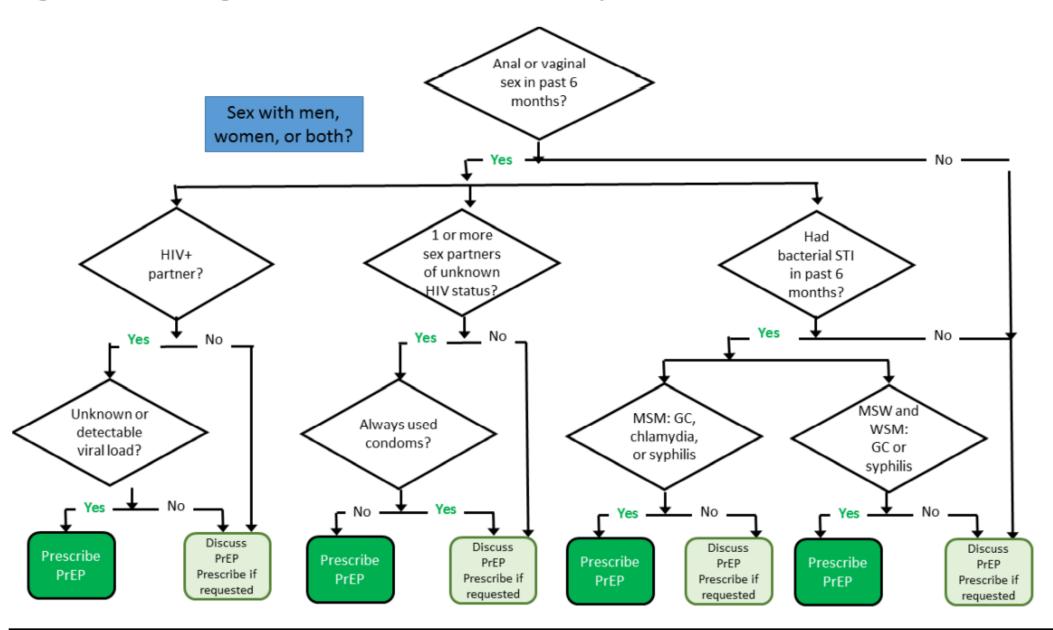
PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

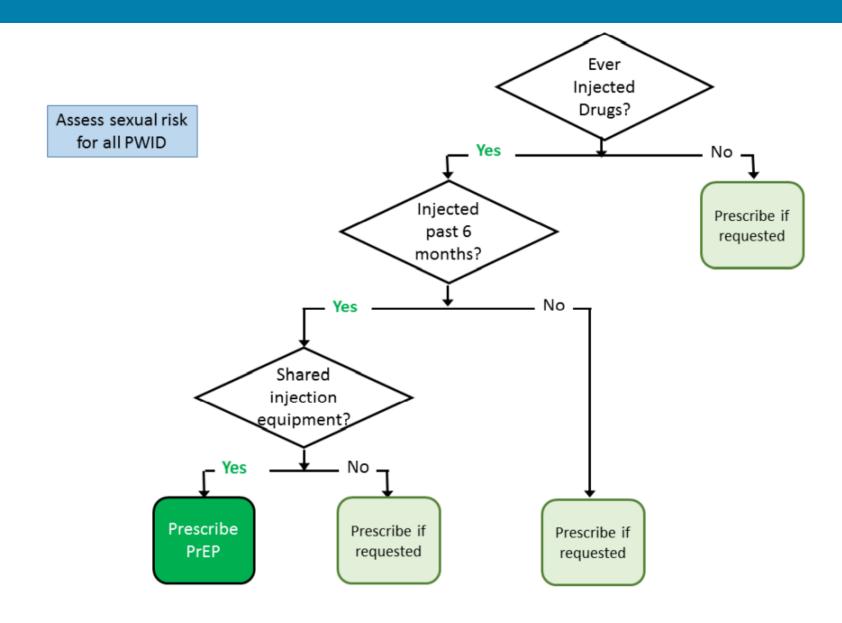
A CLINICAL PRACTICE GUIDELINE





Figure 2 Assessing Indications for PrEP in Sexually Active Persons





HIV Testing for PrEP



- Increasing evidence that antiretroviral use in those with HIV, delay the diagnosis of HIV with Ag/Ab test
 - Cabotegravir: Delay by 35 to 185 days
- For patients who are starting or restarting PrEP after a long stop, test using an HIV antigen/antibody test (laboratory-based is preferred).
 - More recent PrEP use: HIV Ab/Ag
 and RNA

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

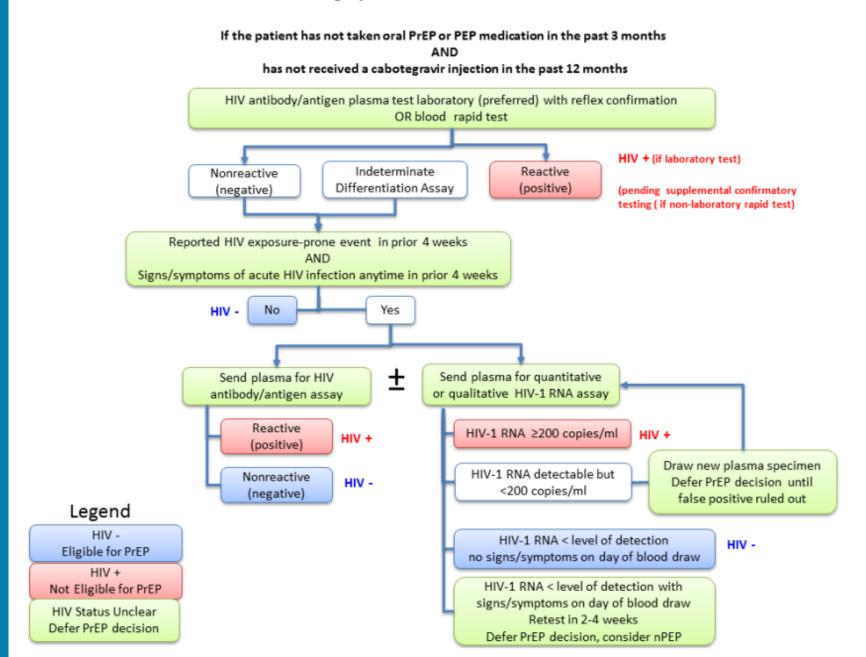
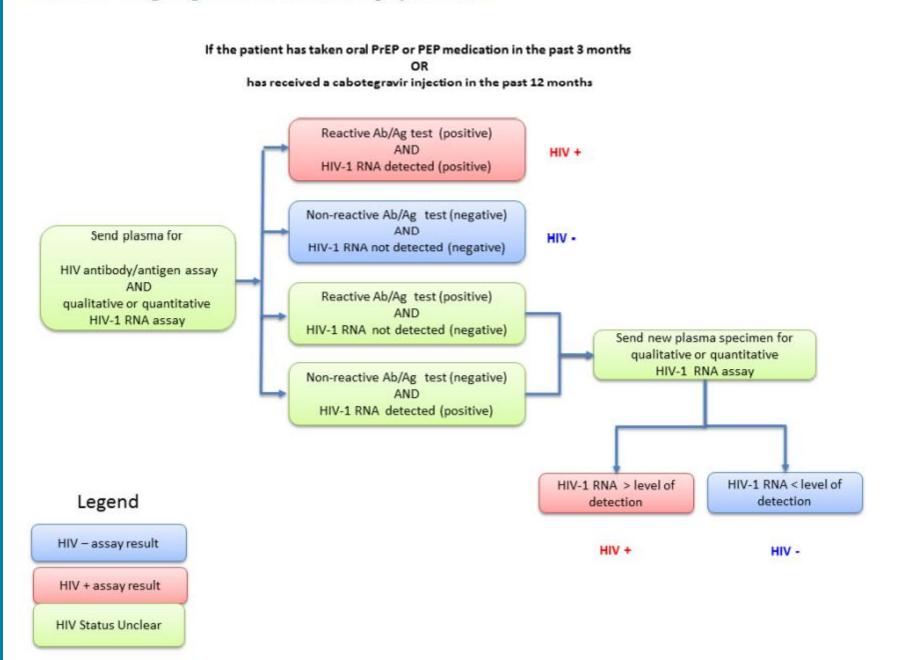


Figure 4b Clinician Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use



Oral PrEP Options



Truvada® or generic equivalent (F/TDF)

 Prescribe to all persons at risk through sex or injection drug use

Descovy® (F/TAF)

- Prescribe to sexually active men and transgender women
 - Not studied for HIV prevention for receptive vaginal sex



Oral PrEP Ongoing Assessments

At First Visit and If At Risk, Every 3 Months

- Hepatitis B Serology*, vaccinate if susceptible
- Hepatitis C Antibody Testing*

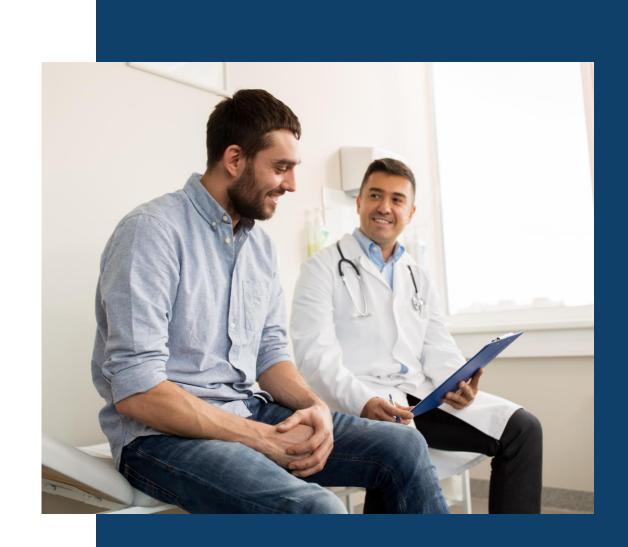
• First Visit & Every Three Months:

- HIV Testing 4th Generation:
- Screen for Symptoms of Acute HIV (fever, rash, headache, sore throat, etc.)
- Three- Site Chlamydia & Gonorrhea Screening; Syphilis Screening
- Pregnancy Screening
- Review the list of medications that may interact with F/TAF or F/TDF

Serum Creatinine

- Contraindicated in CrCl <60 mL/min with F/TDF and F/TAF can be for those with eCrCl of <60 ml/min but ≥30 ml/min.
- Assess creatinine clearance once every 12 months for patients under age 50 or patients whose estimated creatinine clearance was greater than 90 mL/min when they started oral PrEP.
- For all other patients, assess creatinine clearance every 6 months.*
- For patients taking F/TAF, Each year, measure patients' triglyceride and cholesterol levels and their weight.





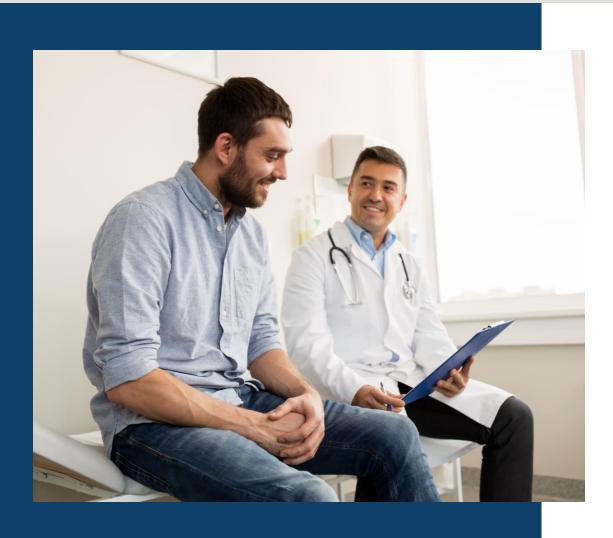
December 20, 2021: FDA Approves Long Acting Injectable for PrEP



- Apretude (cabotegravir extended-release injectable suspension) approved by FDA
- Indicated for adults and adolescents weighing at least 77 pounds who are at risk of sexually acquiring HIV
- Support individuals who medication adherence is an issue.
- 600 mg of cabotegravir injected into gluteal muscle every 2 months is recommended
- 30 mg daily oral cabotegravir is optional for a 4-week lead-in prior to injections.



Injectable (Cabotegravir or CAB) PrEP Ongoing Assessments



- Regular kidney, triglyceride, or cholesterol assessments are not needed for patients taking CAB as they are for patients taking oral PrEP
- First Visit for Everyone
 - HIV Testing HIV Ag/Ab and HIV RNA Screen for Symptoms of Acute HIV (fever, rash, headache, sore throat, etc.)
- MSM and Transgender Women
 - At every injection visit
 - HIV Ab/Ag and HIV RNA
 - Every other month
 - Syphilis, Chlamydia or Gonorrhea
- Heterosexual Women and Men
 - At every injection visit
 - HIV RNA
 - Every other injection visit
 - Syphilis, Gonorrhea
 - Every 12 months
 - Chlamydia



Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually-Active Adults	Persons Who Inject Drugs ¹			
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months ² • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment			
Clinically eligible	ALL OF THE FOLLOWING CONDITIONS ARE MET: Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection No signs/symptoms of acute HIV infection No contraindicated medications or conditions				
Dosage	600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle Initial dose Second dose 4 weeks after first dose (month 1 follow-up visit) Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)				
Follow-up care	At follow-up visit 1 month after first injection HIV Ag/Ab test and HIV-1 RNA assay At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following: HIV Ag/Ab test and HIV-1 RNA assay Access to clean needles/syringes and drug treatment services for PWID At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following: Bacterial STI screening² for MSM and transgender women who have sex with men² – oral, rectal, urine, blood At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following: Bacterial STI screening¹ for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood At follow-up visits at least every 12 months (after the first injection) provide the following: Assess desire to continue injections for PrEP Chlamydia screening for heterosexually active women and men – vaginal, urine At follow-up visits when discontinuing cabotegravir injections provide the following:				

¹ Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

² Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

Additional Prep Options

Same Day PrEP

• Offer same-day PrEP to patients when appropriate. Clinic must have rapid HIV testing, blood draw for creatinine testing and have rapid follow-up with results.

2-1-1 Dosing

- Event Driven, Not FDA Approved
- 2 pills in the 2 24 hours before sex (closer to 24 hrs. preferred), 1 pill 24 hours after the initial two-pill dose and 1 pill 48 hours after the initial two-pill dose
- For individuals who have infrequent sex.
- IPERGAY and Prevenir trial: High protection levels (86%) in those who take 3 to 4 doses per week
- Only for MSM



Everyone Should Be Educated About PrEP



Risk by Sexual Exposure:

- Have HIV+ partner
- One or more partners with unknown HIV Status
- Had bacterial STI in past 6 months
- Anonymous sex partners, use of apps to find sex partners
- Risk by Injection Drug Use:
 - Injected drugs in past 6 months
 - Shared injection equipment



Prevention Option: 6 Months of Protection



- Yeztugo (lenacapavir) injection, 463.5 mg/1.5 mL, is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents (>35kg) who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.
- Approval Based on Phase 3 PURPOSE 1 and PURPOSE 2 Data that Showed ≥99.9% of Participants Remained HIV Negative
- Gilead Advancing Access: Co-Pay Savings & Medication Assistance

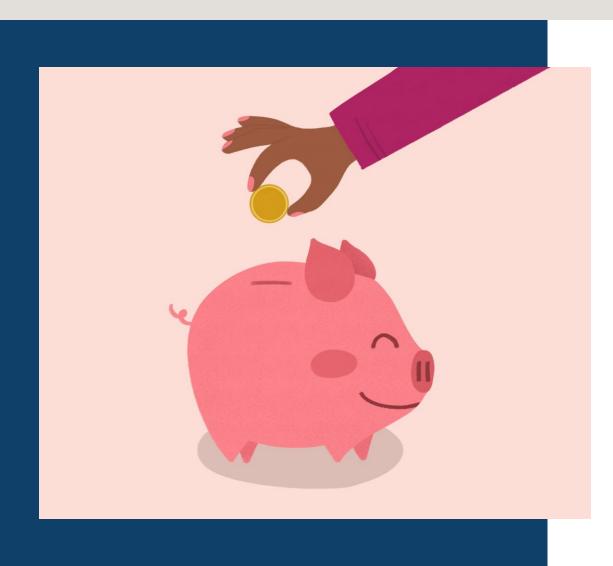


Timing of Biannual Injection



- Dosage: Initiation dosing (injections and tablets) followed by once-every-6-months continuation injection dosing. Tablets may be taken with or without food.
 - **Initiation**: Day 1: 927 mg by subcutaneous injection (2 x 1.5-mL injections) and 600 mg orally (2 x 300-mg tablets). Day 2: 600 mg orally.
 - **Continuation**: 927 mg by subcutaneous injection every 6 months (26 weeks) from date of last injection ±2 weeks.
- Anticipated delayed injections: If scheduled 6-month injection is anticipated to be delayed by more than 2 weeks, tablets may be taken on an interim basis (for up to 6 months) until injections resume. Dosage is 300 mg orally (1 x 300-mg tablet) once every 7 days. Resume continuation injections within 7 days of the last oral dose.

Is Cost Going to Be A Barrier?



- Lenacapavir: \$28,218 per Year
- Cabotegravir: \$24,000 per Year
- Daily Prevention Pills can cost as little as \$1 per dose when purchased as generics



Resources

- NDHHS: www.hhs.nd.gov/HIV
 - Order Prevention Supplies: Brochures, Condoms, Lube, Self-Testing Posters, Safer Sex Kits
 - Lunch and Learns: <u>www.hhs.nd.gov/HIV/Education</u>
 - Resources: <u>www.hhs.nd.gov/HIV/Provider</u>
- National HIV Curriculum: https://aidsetc.org/nhc
- STD Education: www.cdc.gov/std/training/default.htm
- HIV PrEP: www.cdc.gov/hiv/risk/prep/index.html
- STD Treatment Guidelines: <u>www.cdc.gov/std/treatment-guidelines/default.htm/tg2021/default.htm</u>





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for the **United States** 2022–2025



The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance

National HIV Strategic Plan, 2022 - 2025

