Pharmacy Name: _____

Pharmacy Permit Number: _____

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) PROTOCOL
V2
Approved 03/18/2026

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing and administration of pre-exposure prophylaxis (PrEP) for the prevention of human immunodeficiency virus (HIV) infection. The purpose of this protocol is to increase access to and use of PrEP by individuals who are at risk of acquiring HIV.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of HIV PrEP under this protocol, pharmacists must have received education and training in HIV PrEP from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Certification as an HIV Pharmacist (AAHIVP) by the American Academy of HIV Medicine satisfies training requirements. Additionally, pharmacists must maintain knowledge of the current Centers for Disease Control and Prevention (CDC) and US Public Health Service recommendations for HIV PrEP and sexually transmitted infections (STIs).[1]

CRITERIA

Pharmacist(s) authorized to initiate dispensing and administration of PrEP will follow current CDC and U.S. Public Health Service recommendations - Preexposure Prophylaxis for the Prevention of HIV Infection in the United States.[1]

Inclusion Criteria:

Any individual who presents to the pharmacy and meets **ALL** of the following inclusion criteria:

- Age ≥ 18 years
- Weight ≥ 35kg (77 lbs) (current weight determined using pharmacy's scale)
- Documented negative HIV screening within seven days of PrEP initiation
    - Screening using an HIV 1/2 antigen/antibody assay with reflex HIV 1-2 differentiation confirmation OR
    - A point of care finger stick assay utilized for initial screening followed by an antigen-antibody assay due to sensitivity constraints

[1]Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. Preexposure prophylaxis for the prevention of HIV infection in the United States -- 2021 update : a clinical practice guideline. Published December 2021.

- Persons possess substantial and on-going risk of HIV acquisition as determined by meeting the criteria for sexual active patients or patients who inject drugs as listed in Appendix 1 or 2

Exclusion Criteria:

Any individual who meets **ANY** of the following criteria:

- Positive, reactive, or indeterminate HIV screening result
- Weight <35 kg (77 lbs) (current weight determined using pharmacy's scale)
- Symptoms of acute HIV infection within the past month (including but not limited to: fatigue, fever, joint or muscles aches, headache, sore throat, vomiting, diarrhea, skin rash, night sweats, and lymphadenopathy).
- History of a High-risk HIV exposure within the past 72 hours
- Pregnancy
- Known Hepatitis B infection
- Known Hepatitis C infection

All individuals who request PrEP but do not qualify for dispensing under this protocol will be referred to a primary care provider, urgent or emergent treatment facility as clinically appropriate.

The pharmacist is authorized under this protocol to issue an order for required and additional baseline laboratory tests, refer the patient to another provider to acquire the required HIV screening, or may perform a rapid CLIA-waived point-of-care fingerstick HIV screening. The pharmacist must verify appropriate screening has been completed and document test results before providing care under this protocol (see initial lab requirements). If an individual tests positive, reactive, or indeterminate for HIV infection, the pharmacist shall refer the patient to a primary care provider, clinic, or local county health department for confirmatory testing and follow-up care. If the pharmacy is the testing facility, then the reporting duty falls on the facility (902 KAR 2:020). See Appendix 3 for sample language.

MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing and administration of the following FDA approved CDC recommended medications for PrEP:

Oral PrEP			
Medication	**Dose**	**Duration of Therapy**	**Notes**
Emtricitabine/tenofovir disoproxil fumarate *(F/TDF – brand name Truvada® or generic equivalent)*	300 mg/200mg by mouth once daily	Dispense 30-day supply with no refills if baseline labs not completed; or up to 90-day supply if required labs completed. Refill quantity only until next scheduled lab follow-up.	
Emtricitabine/tenofovir alafenamide (*F/TAF –*	200 mg/25 mg by mouth once daily	Dispense 30-day supply with no refills if baseline labs not completed; or up to 90-day	**NOT FDA-approved for individuals assigned female at birth who have**

brand name brand name Descovy®)		supply if required labs completed. Refill quantity only until next scheduled lab follow-up.	**receptive vaginal intercourse.**

Injectable PrEP				
Medication	**Dose**	**Frequency**	**Duration of Therapy**	**Notes**
Cabotegravir extended-release injectable suspension *(CAB - brand name Apretude®).**	One 600mg/3mL gluteal intramuscular injection	Initial dose; Second dose 4 weeks after the first dose; Every 8 weeks thereafter	Administer follow-up injections only if required lab tests are completed including HIV-1 RNA assay	**HIV-1 RNA assay <u>shall</u> be obtained prior to administration.** *Limited data in patients with eCrCl < 15 ml/min and increased monitoring for adverse effects is recommended.* *No data available for patients on dialysis*

**Optional oral lead-in prior to initiation of CAB injections: 30 mg daily of oral cabotegravir is optional for a 4-week lead-in prior to initiating injections to assess tolerability of cabotegravir. Must be dispensed by specialty pharmacy and will require a prescription from prescriber*

Medication	Dose	Frequency	Duration of Therapy	Notes
Lenacapavir injectable solution	927 mg subcutaneous injection (2 x 1.5mL injections)	One dose every 6 months (26 weeks)	Administer follow-up injections only if required lab tests are completed including HIV-1 RNA assay	**All individuals must be screened for HIV-1 infection prior to initiation using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. If an antigen/antibody-specific test is used and provides negative results, lenacapavir can be initiated and results of HIV screen confirmed with HIV-1 RNA**
	Lenacapavir 600 mg orally	600mg orally (2 x 300 mg tablets) on Day of initial injection and day following initial injection	Initiation of therapy	

				assay. *See table for dose adjustments for patients initiating Strong and Moderate CYP3A Inducers Potential exclusion criteria: Patients on a strong or moderate CYP3A inducer

Maintain Scheduled Continuation Injection Dosing	Schedule for <u>Supplemental</u> Doses of Lenacapavir for Patients initiation of **strong** CYP 3A Inducers	
	Time	Dosage
Continue to administer 927 mg subcutaneously, plus administer supplemental doses of lenacapavir	On Day strong CYP3A inducer initiated (at least 2 days after lenacapavir is initiated.)	**Supplemental dosage Step 1**: 927 mg subcutanesouly (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets)
	On day after strong CYP 3A inducer is initiated	**Supplemental dosage Step 2**: 600 mg orally (2 x 300 mg tablets)
	If strong CYP3A inducer co-administered for longer than 6 months	Subsequent supplemental dosage: every 6 months from initiation of strong CPY4A inducer, continue to administer a supplemental dose of lenacapavir as described above
After stopping the moderate CYP3A inducer, continue the once every 6-month scheduled continuation injection dosing of lenacapavir		

<table>
<tr><td rowspan="2">Maintain Scheduled Continuation Injection Dosing</td><td colspan="2">Schedule for <u>Supplemental</u> Doses of Lenacapavir for Patients initiation of moderate CYP 3A Inducers</td></tr>
<tr><td>Time</td><td>Dosage</td></tr>
<tr><td rowspan="2">Continue to administer 927 mg subcutaneously, plus administer supplemental doses of lenacapavir</td><td>On Day moderate CYP3A inducer initiated</td><td>Supplemental dosage: 463.5mg subcutaneously (1x1.5mL injection)</td></tr>
<tr><td>If moderate CYP3A inducer co-administered for longer than 6 months</td><td>Subsequent supplemental dosage: every 6 months from initiation of moderate CPY4A inducer, continue to administer a supplemental dose of lenacapavir as described above</td></tr>
<tr><td colspan="3">After stopping the moderate CYP3A inducer, continue the once every 6 month scheduled continuation injection dosing of lenacapavir</td></tr>
</table>

Contraindications:

- Unknown or positive HIV-1 status

Precautions:

- Residual concentrations of lanacapavir may remain in systemic circulation for up to 12 months or longer after discontinuation.
- Common side effect is injection site reaction including nodules (depot formation) that is palpable at the injection site. Nodules are expected to decrease in size over time.

Procedures for Monitoring:

Same as CAB

PROCEDURES FOR THE INITIATION OF THERAPY

PrEP will be initiated only in carefully selected individuals who are appropriately screened for HIV infection and based on relevant medical and social history as well as consideration of contraindications and precautions. (The CDC Clinicians' Quick Guide for Oral HIV PrEP[2] and Injectable HIV PrEP[3] may be consulted for additional information.)

Oral PrEP <u>cannot</u> be started without an assessment of recent renal function. The pharmacist is authorized under this protocol to issue an order for a basic metabolic panel which includes a serum creatinine assay, to refer the patient to another provider to acquire the necessary testing, and to perform a CLIA-waived point-of-care serum creatinine.

Serum creatinine and creatinine clearance must be documented within three (3) months.

<u>Assess for Relevant Medical and Social History</u>

- Patient demographics and weight
- Sexual practices associated with risk of HIV acquisition (Appendix 1)

[2] https://www.cdc.gov/hivnexus/media/pdfs/2024/04/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-oral-hiv-prep.pdf
[3] https://www.cdc.gov/hivnexus/media/pdfs/2024/04/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf

- Sexual history 5 "Ps" (partners, practices, protection of STIs, past history of STIs, pregnancy intention) Guide to Taking a Sexual History | STI | CDC
- Injection practices for patients who inject drugs (Appendix 2)
- Hep B immunization status
- Current medications
- Renal function
- Medication allergies and hypersensitivities
- Medical history
- Willingness to adhere to PrEP therapy and testing requirements
- Drug-drug interactions

Medication Specific Contraindications and Precautions

Selection of a specific PrEP regimen will be based on patient preference, insurance and financial status, and the following contraindications and precautions:

Contraindications:

- Emtricitabine/tenofovir disoproxil fumarate (F/TDF)
    - Known hypersensitivity to emtricitabine or tenofovir or any component of the formulation
    - Do not co-administer with adefovir, St John's Wort, rifampin, rifabutin, or rifapentine
    - Do not use if eCrCl less than 60 ml/min
- Emtricitabine/tenofovir alafenamide (F/TAF)
    - Known hypersensitivity to emtricitabine or tenofovir or any component of the formulation
    - Do not co-administer with adefovir, St John's Wort, rifampin, rifabutin, or rifapentine
    - Do not use if eCrCl less than 30 ml/min
    - NOT FDA-approved for individuals assigned female at birth who have receptive vaginal intercourse
- Cabotegravir extended-release injectable suspension (CAB)/oral cabotegravir tablet
    - Known hypersensitivity to cabotegravir or any component of the formulation
    - Do not co-administer with carbamazepine, oxcarbazepine, phenytoin, phenobarbital, rifampicin, rifampin, rifapentine

Precautions:

- Emtricitabine/tenofovir disoproxil fumarate (F/TDF)
    - NSAIDs use precaution – may increase the risk of kidney damage in association with tenofovir
        - Counsel patients to limit NSAID use

    - Osteoporosis, pathologic or fragility bone fractures or significant risk factors for osteoporosis
    - Medications that are nephrotoxic or that may decrease bone mineral density.
- Emtricitabine/tenofovir alafenamide (F/TAF)
    - NSAIDs use precaution – may increase the risk of kidney damage in association with tenofovir
        - Counsel patients to limit NSAID use

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSMENT OF THERAPIES

The pharmacist is authorized under this protocol to issue an order for all necessary baseline and follow-up labs or to refer the patient to another provider to acquire necessary testing, or to perform CLIA-waived point of care testing as appropriate.

Additional baseline laboratory tests that must be completed within 30 days of initiating PrEP:

Oral (F/TDF or F/TAF) PrEP:

- Sexually transmitted Infection (STI) testing for syphilis, gonorrhea, and chlamydia *(reactive and indeterminate tests are an automatic referral to the county health department or the patient's healthcare provider for follow-up and confirmatory testing)*
- Hep B serologies- (triple panel test preferred)
- Hep C serologies
- Fasting lipid panel (F/TAF only)
- Pregnancy testing (for individuals who may become pregnant)

Injectable (CAB) PrEP:

- HIV-1 RNA assay
- Sexually transmitted infection (STI) testing for syphilis, gonorrhea, and chlamydia *(reactive and indeterminate tests are an automatic referral to the county health department or the patient's healthcare provider for follow-up and confirmatory testing)*
- Hep B serologies – (triple panel test preferred)
- Hep C serologies
- Pregnancy testing (for individuals who may become pregnant)

Labs for sexually transmitted infections may be ordered as appropriate based on patient history and as outlined in the Centers for Disease Control and Prevention (CDC) and U.S. Public Health Service recommendations for HIV PrEP. See Appendix 3 for sample language.

On-Going PrEP Therapy

Subsequent PrEP may be dispensed and administered only in individuals following assessment of signs and symptoms of acute HIV infection, repeat HIV screening to confirm status, assessment of PrEP tolerability and adherence, and review of additional CDC recommended follow-up lab work for oral or injectable PrEP as indicated in Appendix 4. The pharmacist is authorized under

this protocol to issue an order for the required labs for the continuation of therapy or may refer the patient to another provider for the acquisition of necessary follow-up testing. The pharmacist must verify appropriate labs are complete and document those results. If other required follow-up labs are not complete, the pharmacist may issue up to a 30-supply of PrEP.

Follow-up Lab Monitoring for Oral (F/TDF or F/TAF) PrEP: See Appendix 4

At least every 3 months

- Repeat HIV antigen/antibody screening tests (HIV-1 RNA assay is also recommended if available) and assess for signs or symptoms of acute infection to confirm that patients are still HIV negative
- Test sexually active patients with signs or symptoms of sexually transmitted infections and screen asymptomatic men who have sex with men (MSM) and transgender women (TGW) at high risk for infection (e.g. patients with infection at prior visits or with multiple sex partners

At least every 6 months

- Repeat serum creatinine and creatinine clearance for patients age >50 years or who had a creatinine clearance <90mL/min when they started oral PrEP or as clinically necessary
- Test all sexually active people for syphilis, chlamydia and gonorrhea

At least every 12 months

- Repeat serum creatinine and creatinine clearance for all patients
- Repeat lipid panel and weight evaluation for all patients prescribed F/TAF

Follow-up Lab Monitoring for Injectable (CAB) PrEP: See Appendix 4

At visit 1 month after initial injection (month 1, second injection)

- Repeat HIV antigen/antibody screening AND HIV-1 RNA assay tests and assess for signs or symptoms of acute infection to confirm that patients are still HIV negative

At each bimonthly visit (beginning with the third injection in month 3)

- Repeat HIV antigen/antibody screening AND HIV-1 RNA assay tests and assess for signs or symptoms of acute infection to confirm that patients are still HIV negative

At least every 4 months (every other injection visit, beginning with the 3rd injection in month 3)

- Repeat sexually transmitted infection (STI) screening for men who have sex with men (MSM) and transgender women (TGW)

At least every 6 months (beginning with the 5th injection in month 7)

- Repeat sexually transmitted infection (STI) screening for all heterosexually active people

Follow-up Lab Monitoring Lenacapavir injectable solution:

At each 6-month visit

- Repeat HIV antigen/antibody screening AND HIV-1 RNA assay tests and assess for signs and symptoms of acute injection.
- Repeat sexually transmitted infection screening for all individuals.

Evaluate the need for referral to a primary care provider or specialist for consultation or management of PrEP for any of the following:

- If a patient tests positive for an STI, the pharmacist will refer for confirmatory testing and follow- up care. The pharmacist may still provide PrEP
- If a patient has abnormal renal values and signs of acute renal injury, refer for urgent evaluation
- If a patient wishes to switch from oral to injectable PrEP or vice versa

Referral Resources

- HIV Management Service (Warmline): 800-933-3413
- Pre-Exposure Prophylaxis Service (PrEPline): 855-HIV-PrEP (855-448-7737)
- Perinatal HIV Consultation and Referral Services (Perinatal HIV Hotline): 888-HIV-8765 (888-448-8765)
- Bluegrass Care Clinic: 859-323-5544
- KY AIDS Education and Training Center: (859) 323-9969

In all cases, should follow-up evaluation and monitoring indicate that continued therapy with PrEP is acceptable, all procedures as outlined for initiation of therapies, including testing, education, documentation, and notification, will be followed.

PATIENT EDUCATION REQUIREMENTS

Individuals receiving HIV PrEP therapies under this protocol will receive the following education:

- Medication counseling consistent with state and federal requirements for prescription drug products
- The importance of medication adherence with relation to the efficacy of PrEP and strategies for optimum medication adherence
- Proper use of PrEP medication dosage, schedule, and potential common and serious side effects (and how to mitigate)
- PrEP does not protect against pregnancy or other sexually transmitted infections except HIV
- Upon discontinuation of PrEP, the risk of HIV acquisition returns
- Signs and symptoms of acute HIV infection and recommended actions
- The importance of and requirement for testing (HIV, renal function, hepatitis B, hepatitis

C, sexually transmitted infections)
- The importance of condom use with every sexual encounter
- The use of new needles and injection equipment in all instances with referral information to syringe exchange programs as needed
- For patients receiving injectable PrEP: the long "tail" of gradually declining drug levels when discontinuing injections and the risk of developing a drug-resistant strain if HIV infection is acquired during that time

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives HIV PrEP therapies under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication, and
- Documentation that the patient receiving PrEP was provided with the required education pursuant to this protocol.
- Documentation of history and medical assessment as well as all completion of required lab work.
- Documentation of referrals to medical provider for further evaluation or management of HIV PrEP and other conditions as appropriate.

NOTIFICATION

Pharmacist(s) shall ask all persons tested or receiving therapy under this protocol for the name and contact information of the individuals primary care provider and other appropriate care providers shall provide notification of a summary of the encounter including at a minimum the individual's name, date of birth, HIV test results, other laboratory test results ordered and assessed under this protocol, medication dispensed, and follow-up plan, within two (2) business days. Pharmacist(s) shall also provide notification if therapy is ceased by the individual, or if administration is not warranted under conditions of the protocol, within two (2) business days.

Any individual affirmatively stating that they do not have a primary care provider may still have HIV PrEP therapies under this protocol provided all other applicable requirements of the protocol are met. Pharmacist(s) should utilize referral resources and refer patients to local providers as appropriate.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving PrEP therapy under this protocol within 7 days of initiating dispensing.]

References:

1. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-

guidelines-2021.pdf. Published December 2021.
2. Apretude [package insert]. Research Triangle Park, NC: Viiv Healthcare; 2021.
3. Descovy [package insert]. Foster City, CA: Gilead Sciences; 2021.
4. Truvada [package insert]. Foster City, CA: Gilead Sciences; 2020

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol,

entitled : _____

and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

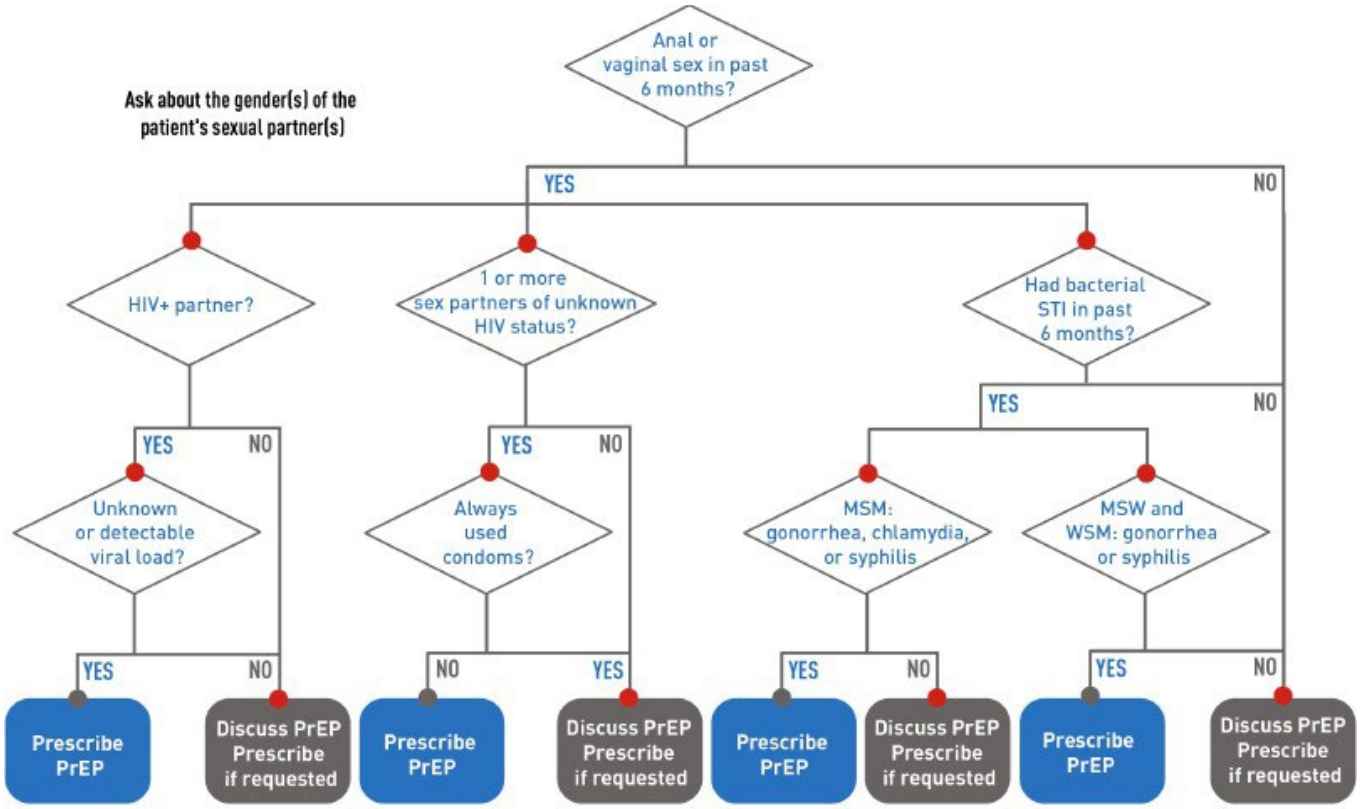
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Appendix 1: Algorithm to Assess Indications for PrEP in Sexually Active Patients (From 2021 CDC PrEP Clinicians' Quick Guide)[4]



MSM: gay, bisexual, and other men who have sex with men

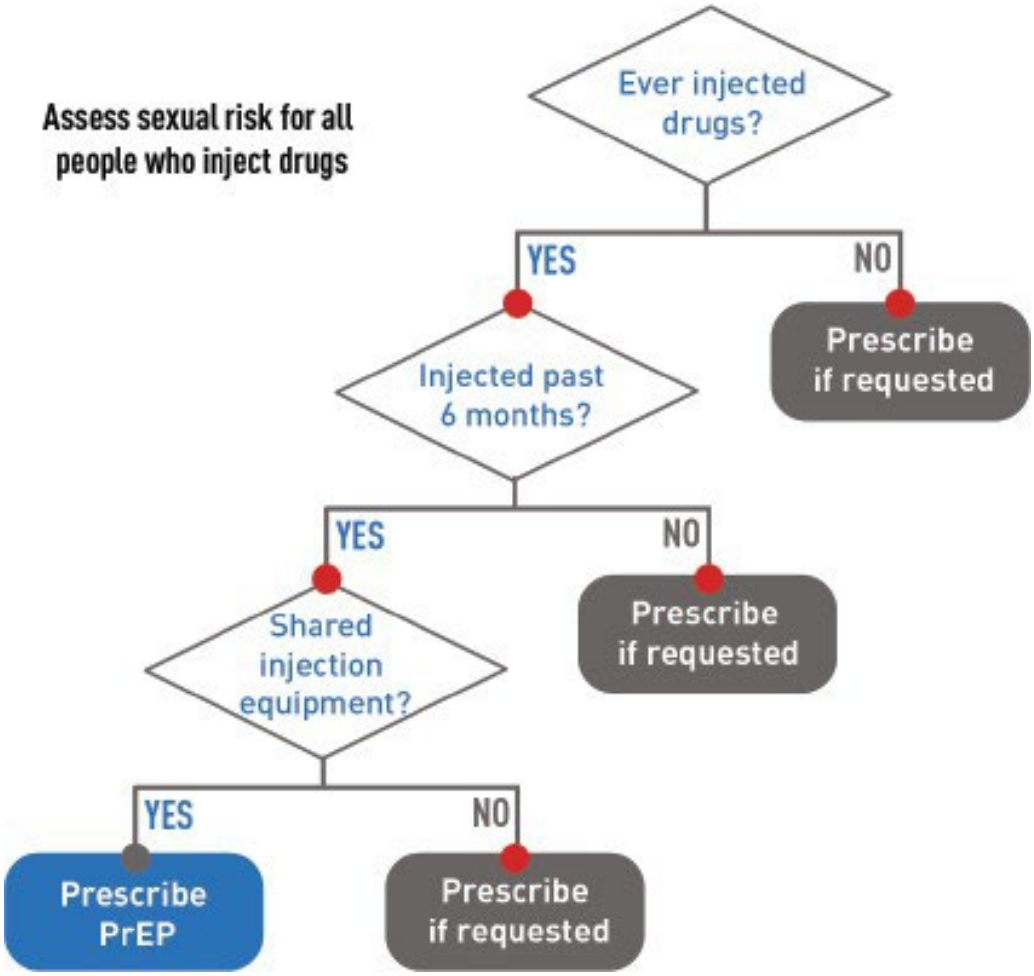
MSW: men who have sex with women

STI: sexually transmitted infection

WSM: women who have sex with men

[4] https://www.cdc.gov/hivnexus/media/pdfs/2024/04/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-hiv-prep.pdf

Appendix 2: Algorithm to Assess Indications for PrEP in Patients Who Inject Drugs (From 2021 CDC PrEP Clinicians' Quick Guide)[2]



Appendix 3: Sample Language

Sample language for reactive or indeterminate HIV tests:

> Your HIV test is reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. Another provider will need to confirm that this is a true result with a more specific test before a diagnosis can be made. You will be referred to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the results. Until you have had your confirmatory test, we recommend you abstain from any condomless sexual activities or other high-risk activities. We will delay starting (or refilling) your PrEP until we have confirmation of the results.

Sample language for reactive or indeterminate STI tests:

> Your STI test is reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). Another provider will need to confirm that this is the true result or to confirm the results with a more specific test before a diagnosis can be made. We are referring you to your health care provider (or your county health department) so that they may perform the necessary testing and clarify the results. Until you have had your follow-up testing, we recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

Appendix 4: Table for Monitoring Oral Therapy and Injectable Therapy

Test	Recommendations for Oral Therapy	Recommendations for Injectable Therapy	Notes
HIV Ag/Ab	Required Baseline + Every 3 months	Required Baseline + Prior to each injection + when stopping CAB	If positive, refer
HIV-1 RNA assay and assess for signs and symptoms of acute HIV infection	Required Every 3 months + when stopping PrEP	Required Baseline + Prior to each injection + when stopping CAB	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Required Baseline + Every 3 months + when stopping PrEP for MSM & TGW Every 6 months for heterosexually active persons	Required Baseline + Every 4 months (starting with 3rd injection) for MSM & TGW Every 6 months (starting with 5th injection) for heterosexually active persons When stopping CAB (only for MSM, TGW)	If positive, refer
Serum creatinine	Recommended Baseline + Every 6 mo. If age ≥50 or eCrCL <90 mL/min at PrEP initiation Every 12 mo. If continuing PrEP + When stopping PrEP		If CrCL <60 mL/min, cannot use F/TDF If CrCL <30 mL/min, cannot use F/TAF If rapid decline in kidney function, consult nephrology
Fasting lipid panel (if taking F/TAF)	Required Baseline, + Every 12 months		
Hepatitis B	Required Completed within 30 days of initiating PrEP	Required Completed within 30 days of initiating PrEP	If positive, refer If negative and clinically appropriate, vaccinate
Hepatitis C	Required Completed within 30 days of initiating PrEP	Required Completed within 30 days of initiating PrEP	
Pregnancy test (for individuals who may become pregnant)	Required Completed within 30 days of initiating PrEP	Required Completed within 30 days of initiating PrEP	
Need to continue PrEP	Recommended if at continued risk Annually	Recommended if at continued risk Annually	Discuss with patient