



2024

Biomedical Prevention Manual of Procedures DPH – Sexual Health Clinics



COUNTY OF LOS ANGELES
Public Health

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What's New in the Biomedical Prevention MOP

What's New in the Biomedical Prevention Manual of Procedures (MOP)

Identification of Patients Who May Benefit from PrEP:

- Persons who requested PrEP were added to all risk groups.
- Any sexually active adult or adolescent should be informed about PrEP.
- All patients seen in the Sexual Health Clinic should be screened for PrEP and PEP in ORCHID. Providers must check the Sexual Health Form before or during the patient visit to determine if PrEP should be discussed with the patient.

PrEP Delivery Sites:

- All DPH sexual health clinics (SHC) are now offering both PrEP and PEP.

PrEP Initiation Visit:

- Clear guidance regarding initiation of PrEP at the initiation visit in patients in which there is not a recently documented HIV test has been added. If there are no contraindications, such as signs of acute HIV infection or history of kidney disease, we recommend **starting the patient on PrEP at the initiation visit** to decrease barriers to accessing PrEP and potentially prevent an HIV seroconversion.

PrEP Referral/Transition to Primary Care:

- All SHCs should now be prescribing PrEP for **1-month** and actively referring patients to the DPH Clinic Services TelePrEP program.

PEP

- All SHCs should now be prescribing PEP for **1-month**. Once the 1-month is completed, if the patient remains HIV negative, they can be transitioned to PrEP for 1 month in the SHC before transitioning to the DPH Clinic Services TelePrEP program

DoxyPEP

- All SHCs can now prescribe DoxyPEP (two 100mg doxycycline pills within 24 to 72 hours of condomless sex) to those at high-risk for STI acquisition (men who have sex with men or transgender women who have had ≥ 1 bacterial STI in the past 12 months or patients who request DoxyPEP even if they have not been previously diagnosed with an STI and/or disclosed their risk status). Providers should dispense #50 tabs at a time.

Advances in PrEP Modalities and Delivery

- Long-Acting Injectable (LAI) PrEP: Cabotegravir (Apretude)
- TelePrEP

Section 1: Program Overview



PrEP & PEP Overview

Introduction

Antiretroviral drugs are an increasingly important component of HIV prevention, as they can reduce viral loads and infectiousness of persons living with HIV (i.e., “treatment as prevention”) and help prevent HIV acquisition in uninfected persons (i.e., “biomedical prevention”). Non-occupational Post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) are two forms of HIV biomedical prevention.

PEP is a 30-day¹ course of three antiretroviral drugs (Tenofovir Disoproxil Fumarate (TDF)/Emtricitabine (FTC) + Dolutegravir or Raltegravir) that must be started within 72 hours of a high-risk HIV exposure to prevent HIV seroconversion. The DPH Sexual Health Clinic PEP regimen includes TDF/FTC once daily + Raltegravir twice daily.

PrEP involves the use of an antiretroviral medication taken by individuals who are HIV-negative and who are at ongoing, elevated risk for HIV infection before they are potentially exposed. PrEP has been shown to reduce the risk of HIV infection by up to 99% when taken consistently. There are two FDA-approved oral regimens for PrEP, both of which are fixed-dose combination tablets: 1) Tenofovir disoproxil fumarate (TDF) and Emtricitabine (FTC) and 2) Tenofovir disoproxil alafenamide (TAF) and Emtricitabine (FTC). Dosing of both regimens is one tablet by mouth once daily. In addition, there is one FDA-approved long-acting injectable regimen for PrEP, which is cabotegravir. There is an optional 4-week oral-tablet lead-in of cabotegravir 30mg once a day prior to initiation of injectable schedule, although many patients prefer to skip the oral lead-in and proceed directly to their first injection. In addition, Cabotegravir 600mg is administered in the gluteal muscle as the initial dose (or after the oral tablet lead-in) with second dose 4 weeks (1 month) after first dose, and then subsequently every 8 weeks (2 months).

DPH currently offers the following regimens:

- *Oral PrEP: TDF/FTC (Truvada), TAF/FTC (Descovy)*
*Descovy is only recommended for men who have sex with men (MSM) and transgender women. It is NOT recommended for persons who were assigned female at birth or persons whose HIV acquisition risk is through receptive vaginal sex.
- *Long-Acting Injectable (LAI) PrEP: Cabotegravir (Apretude)*
- *Oral PEP: TDF/FTC (Truvada) + Raltegravir*

The Clinic Services PEP and PrEP program is designed for patients at high risk for HIV acquisition. Between 2006-2021, men who have sex with men (MSM) accounted for 89% of the new HIV cases in Los Angeles County (LAC). Clients who have a history of injection drug use accounted for the second biggest group, at 5%.

¹ The CDC recommends a 28-day course of 3 anti-retroviral drugs. Since Truvada (TDF/FTC) and raltegravir come in a 30-day supply, for the purposes of this MOP, it will be a 30-day course.

Identification of Patients Who May Benefit from PrEP

The Division of HIV and STD Programs (DHSP) recommends PrEP be considered for the following individuals:

Who is a Candidate for PrEP?	
Sexually Active Adults and Adolescents ²	Persons Who Inject Drugs
<ul style="list-style-type: none"> Any adult or adolescent that requests PrEP can be evaluated irrespective of endorsed risk factors Anal or vaginal sex in the past 6 months; and sexual partner has HIV (especially if the partner has unknown or detectable viral load); or recent bacterial STI in the past 6 months; or history of inconsistent or no condom use with sexual partner(s) 	<ul style="list-style-type: none"> Any adult or adolescent that requests PrEP can be evaluated irrespective of endorsed risk factors Injecting partner has HIV; or shares drug preparation; or injection equipment

² Weight requirement of at least 35 kg (77lb)

PrEP Guidelines for Los Angeles County that describe in more detail who should be considered for PrEP are available at: http://publichealth.lacounty.gov/dhsp/Biomedical/LAC-HIVPrEP-Guidelines_FINAL_10212022.pdf

PrEP Screening should be completed for **every patient** that enters the SHCs. Nurses will complete the Sexual Health Adhoc Form, and if one of the following screeners for heterosexual cisgender women, MSM, transgender women, or people who use drugs is checked, the provider **must** discuss PrEP with the patient. Alternatively, if the patient has a risk factor that is not included, the nurse may type a risk factor into the “Specify risk” field. **Providers must review the sexual health form to ensure appropriate screening and discussions about PrEP occur.**

Sexual Health - ZZZZTEST, ADULTPUMPSEVENTEEN

*Performed on: 10/17/2018 1836 PDT

PrEP Screening

Client ever taken PrEP: Yes No

Client ever taken PEP: Yes No

Client currently taking PrEP: Yes No

Patient referred to PrEP/PEP?: Yes No

Heterosexual Women:

- Reports an HIV positive sex partner
- Reported history of syphilis in past 12 months
- Suspect her male partners may be having sex with men
- Multiple partners (HIV status unknown)
- Exchanged sex for money, drugs, or other goods

MSM/Transgender Women:

- Reports an HIV positive sex partner
- Anogenital STD in 12 months
- Multiple partners (HIV status unknown)
- Reports unprotected anal intercourse
- Prescribed PEP previously and continued high risk behavior
- Exchanged sex for money, drugs, or other goods

Specify Risk:

Drug Users

- IDU (Intravenous Drug use or Injection Drug User) who sharing injection equipment >=1 time per day
- Inject cocaine or methamphetamine
- Use of stimulant drugs

***UPDATE*:** The PrEP Screening Adhoc form noted above is currently being updated to include STDs within the past 6 months (not 12 months).

Delivery Sites

PrEP Delivery Sites within Clinic Services

- Antelope Valley Health Center
- Central Health Center
- Curtis Tucker Health Center
- Hollywood-Wilshire Health Center
- Martin Luther King Jr. Health Center
- North Hollywood Health Center
- Pomona Health Center
- Torrance
- Ruth Temple Health Center
- Whittier Health Center

Interactive map of PrEP delivery sites with key below:

<https://www.google.com/maps/d/viewer?mid=14J8vQyyev0xHRHbN4OXmCTUkWNhsTaCI&hl=en&ll=34.4692194847144%2C-118.15993376464841&z=9>

Blue = DHSP funded site

Red = LA County Sexual Health Clinics

Green = Non-DHSP funded clinics

Purple = PrEP Pharmacy

Duration of PrEP at SHCs

The provision of PrEP at the SHCs is of high public health importance given the high-risk patients seen in the clinics and the low use of PrEP in these patients. In addition, many patients in the community face barriers in accessing PrEP such as financial barriers, poor access to health care, and difficulties obtaining PrEP with their provider. After being initiated on PrEP at SHCs, patients will be referred to the DPH TelePrEP program where they can continue on PrEP or be referred to a PrEP Center of Excellence or their primary care provider. The PrEP navigators within the TelePrEP program ensure that patients who prefer to be referred to a PrEP Center of Excellence or to primary care have a sufficient supply of PrEP to prevent lack of coverage. In 2020, PrEP received a Grade A recommendation from the United States Preventive Task Force, which requires that all insurance providers cover PrEP without any additional costs to the patient, including co-pays, deductibles, and medication costs.

Section 2: PrEP/PEP Service Delivery



PrEP Panel Management

The clinic staff will be responsible for re-engaging patients who have been lost to care as well as the continued treatment of PrEP patients. **Patients should receive a reminder call for their appointment 1 – 2 days prior to their appointment to decrease the no-show rate.**

PrEP ad-hoc forms should be completed in ORCHID during each patient visit.

Staff and Clinic Specific Roles and Responsibilities

Staff Roles and Responsibilities

Role	Responsibility
All Clinic MDs/NPs, RNs, PHIs	<ul style="list-style-type: none"> Screen STD clinic patients for potential PrEP eligibility Refer appropriate patients for PrEP Order appropriate lab work for PrEP visit Patient education about PrEP
PrEP clinic MDs/NPs	<ul style="list-style-type: none"> Determine suitability for PrEP Medical evaluation and follow-up visits PrEP prescription Patient education and adherence counseling Work with team to transition patient to primary care

Clinic Specific Roles and Responsibilities

Duty	Staff Name and Title
Point of Contact for providers wanting to make a referral for PrEP, ensuring warm hand-off (via phone) <ul style="list-style-type: none"> Referrals from Community Providers Referrals from other DPH clinics Referrals of patients from SHC to TelePrEP program 	Front desk
Point of Contact for patients self-referring for PrEP <ul style="list-style-type: none"> Answer patient’s questions Assists in making appointments 	Front desk
Clinic Panel Management (new patients and PrEP initiation visit) <ul style="list-style-type: none"> Patient Tracking Contacting patients with reminders and for broken appts Serves as point person for questions from PrEP patients 	Front desk / Nurse
PrEP Panel Management <ul style="list-style-type: none"> Patient tracking Patient education about PrEP, DoxyPEP, and other prevention tools Contacting patients with reminders, scheduling follow-up labs, and to reschedule appointments Serves as point person for questions from PrEP patients 	PrEP navigators
Adherence Counseling	Provider/PrEP navigator

Risk Counseling	Provider/PrEP navigator
Patient Navigation – lead to assist with the transition to primary care <ul style="list-style-type: none"> • Works with patient to assess the best plan for retention or transition (existing PCP vs TelePrEP vs other) • Communicates with PCP or other providers (providers labs, other documentation as needed) 	PrEP Navigator

Laboratory and Pharmacy Services

Laboratory Services

Laboratory and/or program staff will order and collect specimens according to the schedule outlined in this manual. They will also ensure the specimens are sent to the appropriate laboratory. All labs, except creatinine, can be sent to PHL. Creatinine will be processed at DHS-associated facilities.

Pharmacy Services

PrEP will be available through DPH Pharmacy and is restricted to PrEP services on the formulary. The clinics will maintain strong communication with DPH pharmacy to ensure a durable and sustainable antiretroviral medication supply, and appropriate medication preparation and dispensing, to adequately delivery the PrEP services.

- Patients can receive a 30-day supply upon initiation of oral PrEP.
- PrEP tablets should be taken from their manufacturer labeled bottled and poured into a brown vial with an ORCHID label.
- A medication guide should be given with all PrEP prescription fills and refills.
- The **Emtricitabine/Tenofovir disoproxil fumarate medication guide from Gilead** can be found at: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf
- The **Emtricitabine/Tenofovir alafenamide medication guide from Gilead** can be found at: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_patient_pi.pdf
- A copy of the “**Basics of PrEP**” handout should be offered to the patient (available in English and Spanish) and can be found at: <http://publichealth.lacounty.gov/dhsp/HealthEducationLibrary.htm>

PrEP Referral/Transition to Primary Care

PrEP referrals and transition to primary care are completed by the TelePrEP navigator, as requested by the patient. Clinic staff should refer all patients to the TelePrEP program for additional education and referral.

Oral PrEP Initiation Visit

Medical Assessment

- Obtain a general medical and social history, review of symptoms. Check specifically for:
 - Recent symptoms of a flu or mono-like illness consistent with acute HIV
 - Any history of renal or liver disease or osteoporosis
 - Any significant past medical history (e.g., diabetes, hypertension)
 - Other medications – check for serious drug-drug interactions
 - Ability to take daily medication
- Physical Examination
- All patients with positive screening tests for gonorrhea, chlamydia, and/or syphilis should be treated and followed up in accordance with routine clinic procedures.
- Vaccinations should be provided for clients based on prior vaccination history, vaccine availability, and indication:
 - Hepatitis A and B vaccines – for all PrEP clients if not previously immunized
 - Meningococcal vaccine – all MSM and transgender women on PrEP
 - HPV Vaccine – MSM, transgender women, and cisgender women under 45 years old
 - MPox Vaccines: MSM and transgender persons who had new diagnosis of STI in the past 6 months or multiple sex partners
- Patients can be dispensed PrEP on the first appointment while labs are pending if they have a low likelihood of having acute HIV or significant past medical history of kidney or liver disease. Notify them that if any labs are abnormal, they should expect a phone call and may possibly need to come back for follow-up/discussion.

STI Prevention: DoxyPEP

- Prescribe DoxyPEP (two 100mg doxycycline pills within 24 to 72 hours of condomless sex) to those at high-risk for STI acquisition (men who have sex with men or transgender women who have had ≥ 1 bacterial STI in the past 12 months or patients who request DoxyPEP even if they have not been previously diagnosed with an STI and/or disclosed their risk status). Prescribe #50 tabs at a time. Order can be found in the AMB STI Protocol order set.

Documentation

- Provider to complete the PrEP provider ad-hoc form.
- Nurse to complete the PrEP nursing ad-hoc form.
- Nurse should complete the Sexual Health ad-hoc form if it has not been completed within the past 4 weeks; if there is no Sexual Health ad-hoc form or > 4 weeks since the last form was completed, complete again.

Patient Education: How to Take PrEP

- **Start the conversation:** Start with an open-ended question about PrEP: “What have you heard about PrEP?” or “What do you expect PrEP to do for you?”
 - Many patients will have heard something from friends or on the internet, so good to gauge their baseline level of knowledge and identify any particular questions.
- **How PrEP works**
 - Drug levels build up in your body so that if you are exposed to HIV, it can't replicate and take hold.
 - Explain the three methods of PrEP offered in the sexual health clinic: daily oral PrEP, oralPrEP on-demand (for cis-gender men and TGW who have sex with men only), and LAI PrEP.
 - Oral PrEP takes 7 days for drug levels to reach protective levels for rectal exposures; data suggest for women or persons with vaginas anticipating vaginal exposure, it can take 21 days before adequate drug levels are reached in vaginal tissue. The time to protection for LAI remains unknown, but the majority achieve protective levels by 7 days.
- **Oral PrEP Side Effects**
 - Nausea or loose stools are the most common side effects that usually improve after the first few weeks; please counsel patients that if they can manage to get through those side effects, they should improve after a few weeks as the body adjusts.
 - Some less common side effects include potential mild worsening of kidney function; please counsel patient that they will be screened for kidney problems using labs that are checked every few months while on PrEP
 - There is a chance of mildly decreased bone density with Truvada (TDF/FTC) but no increased use of fractures. There is good evidence that this is reversible, meaning that your bone density will return to its prior level after you stop the medication.
 - For high-risk patients, you can safely counsel them that the benefits outweigh the potential risks.
- **Condoms:** Best to ask an open-ended question: “What have you heard about condoms and PrEP?”
 - Then explain that while PrEP is highly effective against HIV, it doesn't protect you from other sexually transmitted diseases . Also, PrEP and condoms are like seat belts and airbags. They work best together to provide the highest level of protection.
- **Pregnancy**
 - PrEP is safe in pregnancy. PrEP is a Category B medication, which means that no risk was found in animal studies. Women who are requesting PrEP while pregnant should be started on PrEP and encouraged to seek prenatal care. These patients will be closely monitored by the TelePrEP navigator and Telehealth provider.

- PrEP also doesn't prevent pregnancy (for women or persons who are able to get pregnant, discuss additional modes of contraception while on PrEP can be discussed during the visit).
- **Adherence**
 - Ask the patient, "Do you currently take any medications daily?"
 - If yes, what helps you remember to take your pills?
 - If no, when you've taken medications in the past, how did you remember to take them?
 - Helpful strategies may include: using a pillbox, taking PrEP with other daily medications, using a phone alarm, marking doses taken on a calendar, and keeping bottles in a visible location associated with daily activity.
 - One common reason for medication non-adherence is due to unforeseen side effects. It is important to inform the patient of common side effects, such as mild nausea, diarrhea, stomach pain, headaches, and abnormal dreams, and work with them to address these side effects as they develop. Most side effects resolve within the first month of treatment.
 - Explain that PrEP is used to treat people who are HIV positive, but it's not strong enough alone and has to be combined with other HIV medications; if the patient isn't taking the medication regularly (i.e., missed several days in a row) and has a high-risk exposure, the patient shouldn't restart the medication without coming in for an HIV test to make sure they are negative to avoid developing HIV drug resistance
 - As shown in table below, explain what to do if a dose of oral PrEP is missed: Inform patients to take the single missed dose as soon as they remember it unless it is almost time for the next dose. If it is time for the next dose, patients should skip the missed dose and continue with the regular dosing schedule. Doubling of dosing should not occur.

Missed Dose	Recommendation
Dose missed and recalled on same calendar day	Take dose on that day and resume normal dosing thereafter
Dose not recalled on same calendar day as due	Do not double dose, continue next day's dosing
Greater than 5 days of missed doses	Resume with double dose before resuming daily dosing
Greater than 14 days of missed doses	Perform HIV testing before restarting doses

- Teach patients to recognize symptoms of acute HIV infection. Instruct patients to report immediately to a clinic if they develop symptoms compatible with acute HIV infection (fever, fever with a sore throat, fever with a headache, rash)
- **Additional Risk-Reduction Counseling**
 - Ask the patient: What else are you doing to protect yourself from HIV?

- Goals of this conversation should be to do the following:
 - Improve the patient’s self-perception of risk.
 - Support behavior change previously accomplished or attempted by the patient;
 - Identify short-term and long-term risk reduction plans based on the patient’s perceived ability to change their behavior; and
 - Review the nexus between HIV/STD infections and alcohol and drug use.
- For individuals who could benefit from more intensive risk reduction programming, intensive behavioral risk-reduction and substance use treatment programs within LAC can be found online at <http://publichealth.lacounty.gov/sapc/contactus.htm>
- **Follow-up and transition in care: Providers will work in conjunction with assigned navigators to assist with follow up and transition in care.**
 - Confirm a schedule for follow-up in 1 month to assess side effects, adherence, and transition plan.
 - Discuss the importance of regular visits and HIV/STD and safety lab testing on PrEP.
 - Transition to TelePrEP program
 - Explain to patient that they will be scheduled for a phone or video appointment with a PrEP navigator who will help them continue on PrEP.
 - Emphasize the importance of the patient scheduling the appointment at a time when they are available, and answering the phone when called at the scheduled appointment time. The appointment is 30 minutes in duration.

During the call, the PrEP navigator will explain their role and provide additional education about PrEP, PEP, and DoxyPEP, how the TelePrEP program works, how often the patient will require follow-up labs, and help the patient sign-up for patient assistance programs, and coordinate medication refills based on patient’s insurance status and pharmacy preference. Start Patient on PrEP

If there are no contraindications, such as signs of acute HIV infection or history of kidney disease, **start the patient on PrEP at the initiation visit**. Order HIV viral load and other tests (see Laboratory Results Review), obtain an updated cell phone number, and call the patient if HIV results are positive. As the provider will only be giving a 30-day prescription of PrEP, the risk of developing resistance to HIV is **extremely low**. It is essential to recognize that the patients you are seeing are at **high risk** of HIV infection, so crucial to start PrEP as quickly as possible to prevent a new HIV seroconversion.

Laboratory Results Review

Review laboratory results and confirm medical eligibility for PrEP from intake visit. This can be done after the PrEP initiation visit or before starting PrEP. The following provides details guidance to consider when reviewing results.

Tests	Comments & Rationale
HIV Ag/Ab (4 th generation) HIV Viral Load	If the patient is HIV-infected, PrEP is unsuitable because they must receive 3 active HIV medications for treatment. Refer them to HIV medical care.
Creatinine	<p>Use the following online calculator for calculating CrCl: http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault</p> <p>Calculated CrCl should be ≥ 60 ml/min (Cockcroft Gault) to use tenofovir disoproxil fumarate (TDF) safely. Calculated CrCl should be ≥ 30 ml/min (Cockcroft Gault) to use tenofovir alafenamide fumarate (TAF) safely. Patients with CrCl<60 should have the test repeated.</p> <p>Assess the use of potentially nephrotoxic medications (NSAIDs, acyclovir, valacyclovir) and bodybuilding substances (creatine, protein drinks).</p> <p>If repeat CrCl is ≥ 60, the patient may start PrEP. If repeat CrCl is between 30-60 ml/min, then please refer patient to TelePrEP for consideration for Descovy (TAF/FTC) or Apretude (CAB).</p> <p>Creatinine should be documented on the PrEP Provider Ad-hoc form in ORCHID.</p>
Hepatitis B surface antigen and surface antibody	<p>Because PrEP has anti-HBV properties, patients with a positive HBsAg should be encouraged to receive PrEP in a primary care setting, where the liver function can be monitored both during PrEP use and after any PrEP interruptions, and where comprehensive HBV management can occur.</p> <p>Patients who are HbsAg negative should be offered HBV vaccination if not previously infected or immunized.</p>
Hepatitis C Antibody	<p>Although positive Hepatitis C serologies does not affect PrEP administration per say, testing is recommended at least once in a lifetime according to USPSTF. Provider should work with navigator to refer patient to primary care for hepatitis C management. If reactive hepatitis C Antibody, this does not affect PrEP administration. However, patients should be referred to primary care for additional testing to determine whether the patient has cleared infection (25-30% cases) or has chronic hepatitis C.</p>
Pregnancy test for women and persons who are able to get pregnant	<p>Women or persons who are able to get pregnant wishing to use PrEP during pregnancy should be encouraged to receive PrEP in a primary care or HIV specialty clinic (if used as part of an attempt to become pregnant with an HIV positive partner). Patient on PrEP should be counseled and referred for family planning services as an additional form of contraception, in addition to condoms, is highly recommended.</p>

Oral PrEP Schedule and Other Assessments

Table 1. PrEP Schedule of Clinical and Laboratory Evaluations and Other

	PrEP Initiation Visit	1 month Visit *
Risk Assessment		
HIV Risk Behaviors	X	X
HIV Diagnostic		
HIV Testing (4 th gen and VL)	X	
STD Diagnostic		
Urine GC/CT	X	
Rectal GC/CT	X	
Pharynx GC	X	
Vaginal GC/CT	X	
Reverse Syphilis Algorithm	X	
HbsAg	X	
HbsAb	X	
HCV Antibody	X	
Safety Labs		
Creatinine	X	
Urine Pregnancy	X	
Lipid Panel done once a year if on Descovy (TAF/FTC)		
Interventions		
Meds Dispensed/Rx	X	X
Adherence Counseling	X	X
Risk-reduction Counseling (brief)	X	X
Referral to Services: (Intensive Risk-Reduction, Substance Use, Mental Health)	X ^a	X ^a
Vaccination (if indicated)	X	X
^a if indicated based on risk assessment. * optional visit, only if additional time is needed to transition the patient		

Oral PrEP Service Delivery Checklist

PrEP Initiation Visit Checklist

(Complete *PrEP Ad-hoc forms* – and *Sexual Health Form* in *ORCHID* if not completed in past four weeks)

- _____ Obtain past medical history. Query specifically about history of kidney and liver (e.g., hepatitis B) disease, bone disease, and fractures. For women or persons who are able to get pregnant and that are of childbearing age, assess pregnancy desires.
- _____ Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- _____ Order all laboratory results to assess for contraindications. If laboratory tests were performed, review at this visit.
 - HIV Viral Load and HIV Ag/Ab
 - STD (GC/CT, Syphilis Serologies) (if not performed in the last month)
 - Serum Creatinine to calculate CrCl
 - HbsAg and HbsAb and HCV Ab
 - Check patient weight for CrCl
 - Pregnancy test (if applicable)
- _____ PrEP education/counseling with patient; ask questions to elicit patient understanding. Ensure all questions are answered regarding substance use and mental health needs and that referrals are made as appropriate.
- _____ Provide bottle of PrEP (#30 tabs) or write prescription for one-month supply.
- _____ Review the importance of regular clinic follow-up and ask the patient about the best method of communication for reminders (call, email, text). Schedule follow-up visit for 1-month and provide PrEP services appointment card PRN.
- _____ Start Hepatitis B vaccine series, administer meningococcal and HPV vaccinations, as indicated.
- _____ Review any lab results after the visit, as needed, and calculate CrCl. If the patient is HIV positive, call the patient to tell them to stop the medication. Make appropriate arrangements for follow-up based on the patient's needs. If patient has CrC < 60 but > 30, then can refer patient to TelePrEP program for Descovy (TAF/FTC) or Apretude (CAB).
- _____ Discuss transition to non-STD clinic medical provider or PCP for ongoing PrEP. Share a list of PrEP providers with patients and tell them to schedule an appointment.

LAI PrEP: Apretude (Cabotegravir)

Background: Apretude (cabotegravir) is a long-acting injectable medication that can prevent HIV transmission and is indicated for people at high risk of HIV exposure.

Route of Administration: Intramuscular (IM) injection that must be given in the muscles of the buttocks

Duation: Start once a month for two months (total of two injection) and then moving forward every two months

Most Common Side effects: Pain and swelling at the site of injection

Maximal Effectiveness: The maximum protection is unknown at this time, but the majority of people should reach maximum protection levels 7 days from receiving injection

Clinic Specific Considerations for Apretude (Cabotegravir)

- Refer all patients who are interested in Apretude to the Business Office to book an appointment with the TelePrEP navigator
- TelePrEP team will work with the patient and clinic staff to have the injection administered at a SHC
- Determine insurance status (Medi-Cal, No Insurance, Private Insurance) and follow the appropriate workflow noted below in order to obtain Apretude
- Labs for initial injection, including an HIV viral load, should ideally be done 7 days prior to first injection¹. Once the initial injection is complete, the follow-up labs can be done at the scheduled injection visits.

¹ Centers for Disease Control and Prevention (CDC). [Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline.](#)

Apretude Order Workflow for Patients with Medi-Cal Insurance

- When patients show interest in Apretude, TelePrEP navigator will inform the Telehealth providers about patient's interest in the injection along with the insurance type (Medi-Cal).
- Navigator will collect patient's Medi-Cal ID and demographic information, including phone and email contact information; aside from the clinic staff who will receive the coordinated medication delivery by the navigator. Document the clinic staff member that will receive the medication.
- Telehealth provider will place the order in ORCHID to a specialty pharmacy
- TelePrEP Team will contact specialty pharmacy to coordinate medication delivery and will ask for medication tracking number.
- TelePrEP team will send an email to the SHC where the patient will receive their medication to provide shipping information and confirmation of clinic. If consent form from Walgreens is requested for patient signature, this email will include it.
- Clinic team will email and/or send an ORHID message to Navigator team of medication received.
- Telehealth provider will send a communicate order instructing clinic nurse to administer the medication once received.
- TelePrEP Team will notify the TelePrEP provider and call the patient and schedule for the SHC Nurse Visit appointment with the Business Office Appointment comment will say 'Apretude PrEP patient'
- TelePrEP navigator will work with B.O to schedule the initial injection, one month injection, and follow up injections.
- Navigator will speak to patient days before the injection with instructions and Apretude Document. TelePrEP team will email the Apretude-one page form to the clinic team to provide to the patient on the day of administration.

Apretude Order Workflow for Patients with No Insurance or Private Insurance

- When patients show interest in Apretude and have private insurance or are uninsured, TelePrEP navigator will inform the Telehealth providers about patient's interest in Apretude during the call.
- Navigator will collect patient's Medi-Cal ID and demographic information, including phone and email contact information; aside from the clinic staff who will receive the coordinated medication delivery by the navigator. Document the clinic staff member who will receive the medication.
- TelePrEP Navigator will log in to ViiV Connect to complete the application for Apretude. TelePrEP nurse will ask patient for number of people in the household along with yearly income.
 - If patient is uninsured, telePrEP navigator will apply for Patient Assistance Program using the ViiV connect portal
 - Navigator will complete the form, sign, and then provide PDF version to Dr. Moore or Telehealth provider
 - Telehealth provider will print, physically sign the form, and will provide it to the navigator for faxing
 - Navigator will provide patient with link to e-sign the application:
<https://www.viivconnect.com/for-patients/esign/>
- Clinic Team will fax any forms received from ViiV to Giovanna and Dr. Moore
 - Fax must be received in clinic due to ViiV's process. However, moving forward TelePrEP team will ensure that the form is fully completed before faxing to ViiV.
- Once ViiV Connect confirms patient enrollment and prescription, TelePrEP Team will contact specialty pharmacy to coordinate medication delivery and will ask for medication tracking number.
- TelePrEP team will send an email to the SHC where the patient will receive their medication to provide shipping information and confirmation of clinic. If consent form from Walgreens is requested for patient signature, this email will include it.
- Clinic team will email and/or send a ORHID message to Navigator team of medication received.
- Telehealth provider will send a communicate order instructing clinic nurse to administer the medication once received.
- TelePrEP Team will notify the TelePrEP provider and call the patient and schedule for the SHC Nurse Visit appointment with the B.O. Appointment comment will say 'Apretude PrEP patient'
- TelePrEP navigator will work with B.O to schedule the initial injection, one month injection, and follow up injections.
- Navigator will speak to patient days before the injection with instructions and Apretude Document. Navigator will ask patient if they would prefer a physical copy of the document. If so, TelePrEP team will email the form to the clinic team to provide to the patient on the day of administration.

Apretude Injection Day Considerations

- Patient will check in to clinic to receive injection.
- In clinic nurse should provide Consent form, if this was requested by the TelePrEP team via email
- Business office/In clinic nurse will scan the document to Giovanna Lopez: Glopez2@ph.lacounty.gov and navigator assigned to patient.
- TelePrEP Team will send the signed consent form back to Walgreens Pharmacy
- TelePrEP Navigator will check in with patient and ask patient for availability for next dose (2nd injection- one month apart).
- TelePrEP Navigator will schedule next appointment with B.O and cycle will repeat

LAI PrEP Schedule and Other Assessments

Table 2. LAI PrEP Schedule of for injections, labs, and telehealth provider visits

Provider note: HIV VL lab for initial injection should ideally be done 7 days prior to first injection¹. Once the initial injection is complete, the follow-up labs can be done at the scheduled injection visits.

Time	≤ 7 days	Day 1	Month 1	Month 3	Month 5	Month 7	Month 9	Month 11	Month 12
Injection		x	x	x	x	x	x	x	
HIV Ag/Ab		x	x	x	x	x	x	x	
HIV VL	x		x	x	x	x	x	x	
STD Testing				MSM, TGW		MSM, TGW, HSM, HSW		MSM, TGW	HSM, HSW: Chlamydia screening
Telehealth Visit			x	x			x		x

MSM = Men who have sex with men, TGW = Transgender women, HSM = Heterosexual men, HSW = Heterosexual women

Bacterial STI Screening every 4 months starting in Month 3 for MSM and TGW

Bacterial STI Screening every 6 months starting in Month 7 for HSM and HSW

LAI Aftercare and Counseling: The most common side effects are pain and swelling at the injection site. In addition, some other common side effects include nausea, vomiting, diarrhea, headache, fevers/chills. Please counsel the patient on taking an over the counter pain medication such as acetaminophen or naproxen within a couple of hours or soon after the injection and continue for 1-2 days as needed. Also, recommend for the patient to apply a warm compress or heating pad to the injection site as needed.

¹ Centers for Disease Control and Prevention (CDC). [Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline.](#)

LAI Missed Doses

The importance of adherence to the injection schedule should be discussed with patient. A missed dose can be discussed in terms of a planned missed injection and unplanned missed injection.

Planned Missed Injection

If the scheduled every 2-month continuation injection visit is missed by more than 7 days, then take once-daily oral 30mg cabotegravir for a duration of up to 2 months to replace 1 missed scheduled every-2-month injection. The first dose should be started on the day of scheduled continuation injection visit.

Unplanned Missed Injection

If the scheduled continuation injection is missed or delayed by more than 7 days and oral cabotegravir has been taken, the patient will need to be clinically reassessed to see if resuming Apretude is appropriate. Please refer to the table below from Apretude’s prescribing information

(https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF)

Table 3: LAI PrEP Missed Doses Management

Table 3. Injection Dosing Recommendations after Missed Injections

Time since Last Injection	Recommendation
If second injection is missed and time since first injection is:	
Less than or equal to 2 months	Administer 600-mg (3-mL) gluteal intramuscular injection of APRETUDE as soon as possible, then continue to follow the every-2-month injection dosing schedule.
Greater than 2 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by a second 600-mg (3-mL) initiation injection dose 1 month later. Then continue to follow the every-2-month injection dosing schedule thereafter.
If third or subsequent injection is missed and time since prior injection is:	
Less than or equal to 3 months	Administer 600-mg (3-mL) intramuscular injection of APRETUDE as soon as possible, then continue with the every-2-month injection dosing schedule.
Greater than 3 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by the second 600-mg (3-mL) initiation injection dose 1 month later. Then continue with the every-2-month injection dosing schedule thereafter.

LAI PrEP Service Delivery Checklist

- _____ Obtain past medical history. For women or persons who are able to get pregnant and that are of childbearing age, assess pregnancy desires.
- _____ Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- _____ Order all laboratory results as noted in Table 2. If laboratory tests were performed, review at this visit.
- _____ PrEP education/counseling with patient; ask questions to elicit patient understanding. Ensure all questions are answered regarding substance use and mental health needs and that referrals are made as appropriate.
- _____ Provide injection per the schedule in Table 2 and review LAI aftercare/counseling
- _____ Review the importance of regular clinic follow-up and ask the patient about the best method of communication for reminders (call, email, text). Schedule follow-up visit for 1-month and then every 2 months per the injection schedule in Table 2. Provide PrEP services appointment card.
- _____ Determine if patient will have any missed appointments if possible to ascertain and follow recommendations in Table 3.
- _____ Start Hepatitis B vaccine series, administer meningococcal, HPV, and Mpox vaccinations, as indicated.

STI Prevention

Discuss STI Prevention and prescribe DoxyPEP if interested (MSM, TGW). Prescribe DoxyPEP (two 100mg doxycycline pills within 24 to 72 hours of condomless sex) to those at high-risk for STI acquisition (men who have sex with men or transgender women who have had ≥ 1 bacterial STI in the past 12 months or patients who request DoxyPEP even if they have not been previously diagnosed with an STI and/or disclosed their risk status).

PrEP On-Demand (PrEP 2-1-1 Regimen)

Intermittent or “On Demand” PrEP, also known as the 2-1-1 regimen, is a non-daily PrEP regimen in which a person takes Tenofovir Disoproxil Fumarate (TDF)/Emtricitabine (FTC) prior to planned sexual intercourse. Specifically, this process requires that the patient take 2 pills of TDF/FTC within 2 – 24 hours prior to first sexual intercourse, then 1 pill every 24 hours during the period of sexual activity until one pill 24 hours after the last sexual intercourse, and one last pill another 24 hours later. This strategy has been studied in MSM in two key trials, IPERGAY and Prévenir, which showed high preventive efficacy of 86% and 99%, respectively. A recent study evaluating the use of 2-1-1 among patients in a clinical practice setting (Kaiser Permanente San Francisco) in 279 patients found no new HIV infections among patients using 2-1-1. The International Antiviral Society-USA endorsed 2-1-1 for MSM who engage in infrequent sexual intercourse. As the FDA has not approved this dosing, it is considered “off-label” dosing; however, CDC has issued clear guidance on its use, which is summarized below:

- Clinicians who elect to provide the 2-1-1 regimen should prescribe no more than **30** pills without follow-up and documentation of another negative HIV test. Patients having sex less than once weekly will have sufficient medication to cover up to 7 intermittent sexual events.
- 2-1-1 should be offered to **cisgender men or transgender women (not on hormones) who have sex with men**, as this regimen has only been studied in MSM. There is also concern that masculinizing hormones (i.e., testosterone) and feminizing hormones (i.e., estradiol) may decrease levels of TDF/FTC in the bloodstream when it is given intermittently, so daily or injectable PrEP are the preferred strategies for transgender people.
- As TDF/FTC was studied for use as 2-1-1, it is the only medication that should be used for this purpose. Tenofovir alafenamide/Emtricitabine should **not** be prescribed for 2-1-1 due to the lack of published efficacy data regarding this regimen.
- 2-1-1 should not be prescribed to MSM with active hepatitis B due to concern for flare.

Discussing 2-1-1

Particular emphasis should be placed on this option for MSM who meet at least one of the below criteria:

- Not having sex regularly
- Ability to plan when having sex (Ex. Long distance relationship, seeing a partner once a month, and not having sex with other partners in-between visits)
- Concern for long-term side effects of taking PrEP daily
 - NOTE: Although no data supports this concern, it has been raised in studies and real-world clinical settings.
- Concern for the ability to adhere to daily PrEP

How to take PrEP On-Demand?

If patient has sex **on one calendar day**, they should take:

- 2 pills at least 2 to 24 hours before sex.
- 1 pill 24 hours after the first dose.
- 1 pill 24 hours after the second dose.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		SEX @ 8:00 PM  Take no later than 6:00 pm.	 Take 24 hours after <u>first</u> dose.	 Take 24 hours after <u>second</u> dose.		

If patient is going to have multiple sexual exposures, they should continue to take a single PrEP pill every 24 hours until they have taken two additional doses, 24 hours apart, after their last sexual exposure. (See example below.)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
SEX @ 9:00 PM  Take no later than 7:00 pm.	SEX (anytime)  Take 24 hours after <u>first</u> dose.	SEX (anytime)  Take 24 hours after <u>second</u> dose.	 Continue to take 24 hours after <u>last dose</u> .	 Take <u>final dose</u> 24 hours after last dose.		

Note: PrEP On-Demand should only be used for spontaneous, planned sex. If patient is using PrEP On-Demand regularly, consider discussing Daily PrEP as an option to increase their protection against HIV.

For more information, see the [PrEP Options That Fit Your Sex Life](#) Fact Sheet (Aug 2022).

Post-Exposure Prophylaxis (PEP): Management of Patients with Recent High-Risk Exposure

HIV post-exposure prophylaxis (PEP) is a 3-antiretroviral medication regimen taken for 28 days that can be utilized for management of patients with who are currently not on PrEP and seek care within 72 hours after an isolated sexual or injection-related potential HIV exposure¹. PEP . PEP is to be utilized in emergency situations. It is not 100% effective at preventing HIV, but should be initiated early on after the exposure to be more effective^{1,2}. If patient has high-risk exposures occur on a regular basis, and the person is determined not to have HIV infection, clinicians should begin PrEP immediately. If the exposure is an isolated event, such as sexual assault or condom failure, PEP should be prescribed, but PrEP is not indicated until after completing the 30-day PEP course.

PEP Indications:

- Condomless anal or vaginal sex within the past 72 hours with a suspected HIV-positive or HIV-unknown partner
- Shared a needle or other equipment for drug preparation within the past 72 hours with a suspected HIV-positive or HIV-unknown partner
- Sexual assault within the past 72 hours

¹ James O. Kahn, Jeffrey N. Martin, Michelle E. Roland, Joshua D. Bamberger, Margaret Chesney, Donald Chambers, Karena Franses, Thomas J. Coates, Mitchell H. Katz, Feasibility of Postexposure Prophylaxis (PEP) against Human Immunodeficiency Virus Infection after Sexual or Injection Drug Use Exposure: The San Francisco PEP Study, *The Journal of Infectious Diseases*, Volume 183, Issue 5, 1 March 2001, Pages 707–714, <https://doi.org/10.1086/318829>

² Roland ME, Neilands TB, Krone MR, Katz MH, Franses K, Grant RM, Busch MP, Hecht FM, Shacklett BL, Kahn JO, Bamberger JD, Coates TJ, Chesney MA, Martin JN. Seroconversion following nonoccupational postexposure prophylaxis against HIV. *Clin Infect Dis*. 2005 Nov 15;41(10):1507-13. Doi: 10.1086/497268. Epub 2005 Oct 13. PMID: 16231265.

³ Centers for Disease Control and Prevention, US Department of Health and Human Services: Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or other Nonoccupational Exposure to HIV, United States, 2016. Link: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

Medications utilized for a PEP are a 30-day course of 3-antiretroviral medications, which are listed as follows for adults and adolescents ≥ 13 years of age³:

Creatinine Clearance (CrCl) ≥ 60 ml/min

Preferred Regimen

- *Tenofovir disoproxil fumarate (TDF) 300mg with Emtricitabine (200mg) once daily PLUS Raltegravir 400mg twice daily or dolutegravir 50mg daily*

Alternative Regimen

- *Tenofovir disoproxil fumarate (TDF) 300mg with Emtricitabine (200mg) once daily PLUS darunavir 800mg AND ritonavir 100mg once daily*

Creatinine Clearance (CrCl) ≤ 59 ml/min

Preferred Regimen

- *Zidovudine and lamivudine with both doses adjusted to degree of renal function PLUS Raltegravir 400mg twice daily or dolutegravir 50mg once daily*

Alternative Regimen

- *Zidovudine and lamivudine with both doses adjusted to degree of renal function PLUS darunavir 800mg AND ritonavir 100mg once daily*

See Table 2: PEP Schedule and Other Assessments below for a list of laboratory testing that should be completed at the time of initiating PEP.

- Prescribe a 30-day course of Tenofovir disoproxil fumarate/emtricitabine (30 tabs) + Raltegravir (60 tabs) while the labs are pending. **Administer the first dose of PEP while the patient is in the clinic.**
- Counseling should be geared towards the importance of adherence to these medications and note to the patient that they must take Raltegravir twice a day. In addition, discuss the side effects of the medications such as nausea, diarrhea, headache, abdominal pain, and fatigue.
- When the labs return, check for any contraindications, including positive HIV test and renal dysfunction (CrCl < 60).
- Have the patient return in 1 month for evaluation. Complete the same tests as the 1 month PrEP visit.
- Discuss the potential need for PrEP.

If the patient presents to the clinic **outside** 72 hours of a high-risk exposure, complete a routine STD clinic visit and assess eligibility for PrEP.

Persons who repeatedly seek PEP should be evaluated for possible PrEP use after confirming they have not acquired HIV infection. Because HIV infection has been reported in association with exposures soon after an PEP course, daily PrEP may be more protective than repeated episodes of PEP.

PEP Schedule and Other Assessments

Table 2. PEP Schedule of Clinical and Laboratory Evaluations and Other

	PEP Initiation Visit	4-6 weeks after exposure	12 weeks (3 months) after exposure
Risk Assessment			
HIV Risk Behaviors	X	X	X
HIV Diagnostic			
HIV Testing (4th gen and VL)	X	X	X
STD Diagnostic			
Urine GC/CT	X	X ^a	
Rectal GC/CT	X	X ^a	
Pharynx GC	X	X ^a	
Vaginal GC/CT	X	X ^a	
Serum RPR	X	X ^a	
HBsAg	X		
HBsAb	X		
HBcAb	X		
HCV Antibody	X		
Safety Labs			
Creatinine	X	X ^c	
AST, ALT	X	X ^c	
Urine Pregnancy	X	X	
Interventions			
Meds Dispensed/Rx	X		
Adherence Counseling	X	X	X
Risk-reduction Counseling (brief)	X	X	X
Referral to Services: (Intensive Risk-Reduction, Substance Use, Mental Health)	X ^b	X ^b	X ^b
Vaccination (if indicated)	X	X	X
Progress on Transition to Primary Care	X	X	X
^a : if not given presumptive treatment at baseline or symptomatic at follow up visit ^b : if noted on risk assessment ^c : For persons prescribed tenofovir DF + emtricitabine + raltegravir OR tenofovir DF+ emtricitabine + dolutegravir			

PEP Service Delivery Checklist

PEP Initiation Visit Checklist

- _____ Perform an HIV risk assessment to determine whether PEP is indicated for the patient. (\leq 72 hours since substantial HIV exposure)
- _____ Provide basic education about PEP. (Refer to Basics of PEP document)
- _____ Obtain past medical history. Query specifically about history of kidney and liver (e.g., hepatitis B) disease, bone disease, and fractures. For women or persons who are able to get pregnant and are of childbearing age, assess pregnancy desires.
- _____ Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- _____ Order all laboratory tests below:
 - HIV test: 4th generation Ag/Ab test and VL
 - STD (GC/CT urine or vaginal, GC/CT rectum, GC pharynx, Syphilis serologies)
 - Serum Creatinine to calculate CrCl
 - AST, ALT
 - HBsAg, HBsAb, HBcAB and HCV Ab
 - Check patient weight for CrCl
 - Pregnancy test (if applicable)
- _____ Order and dispense Tenofovir disoproxil fumarate (#30 tabs) + Raltegravir (#60 tabs)
- _____ Provide PEP education/counseling to patient; ask questions to elicit patient understanding.
- _____ Emphasize the importance of adherence to medication and return to the clinic at 1 month for a repeat HIV test. Inform the patient that they will be notified if their initial HIV test returns positive, which would require changing their medications from PEP to HIV treatment.
- _____ Order 1-month follow-up visit
- _____ Offer Hepatitis A/B vaccine series, administer meningococcal, HPV, MPox vaccinations, as indicated.
- _____ Review any lab results after the visit, as needed, and calculate CrCl. If the patient is HIV positive or CrCl $<$ 60, call the patient to tell them to stop the medication. Make arrangements for follow-up based on the patient's needs. Work with DHSP and PHI to link patients to LA County DHSP Rapid and Ready Program.

1- and 3-Month Follow-Up Appointments

- _____ Assess the following at this visit:
 - Patient's risk behavior and desire to start PrEP
 - Medication adherence over the past month
 - Signs/symptoms of acute HIV
 - Possibility of pregnancy (if applicable)
- _____ Order all laboratory tests below:
 - HIV test: 4th generation Ag/Ab test and HIV VL
 - STD (GC/CT urine or vaginal, GC/CT rectum, GC pharynx, Syphilis serologies)
 - Serum Creatinine (1 month only)
- _____ **If the patient is interested in starting PrEP, provide basic education about PrEP (Refer to Basics of PrEP document).**
- _____ Order and dispense TDF/FTC (#30 tabs)
- _____ Provider will refer patient to TelePrEP program.

Section 3: Clinical Considerations and Referrals



Management of Suspected Acute Seroconversion (Acute HIV)

Signs and symptoms of acute HIV are listed below in Table 2. Should a patient taking PrEP present with signs and symptoms consistent with acute HIV, this should trigger an immediate referral to HIV specialty care for appropriate evaluation. Providers should also order an HIV Antibody/Antigen and HIV viral load at the time of the visit. PrEP medications should be continued pending the return of laboratory tests and expert clinician guidance.

Common Symptoms of Acute HIV
Fever
Fatigue
Rash
Headache
Lymphadenopathy
Pharyngitis
Myalgia or arthralgia
Nausea, vomiting, or diarrhea
Night sweats

If patient had no previous oral PrEP or PEP use in the past 3 months OR CAB injection in the past 12 months, then:

- Suspect acute HIV and review above symptoms with patient
- If patient endorses any of the symptoms above in the past 4 weeks and reported an exposure in the past 4 weeks, then order a HIV Ag/Ab with Viral load

If patient had previous oral PrEP or PEP use in the past 3 months OR CAB injection in the past 12 months, then:

- Order HIV Ab/Ag and with Viral Load

During regular business hours, Monday - Friday, the *UCSF Clinician Consultation Center PrEPline (855-448-7737)* is available to answer a range of questions for clinicians regarding PrEP management. DHSP Medical Directors and Associate Medical Directors are also available for PrEP questions.

Adverse Drug Reactions

Patients taking PrEP should be informed of side effects among participants in clinical trials. In these trials, side effects were uncommon and usually resolved within the first month of taking PrEP (“start-up syndrome”). Clinicians should discuss the use of over-the-counter medications for headaches, nausea, and flatulence should they occur. Patients should also be counseled about signs or symptoms that indicate a need for urgent evaluation (e.g., those suggesting possible acute renal injury or acute HIV infection).

In the event of intolerance, including but not limited to rash, nausea, vomiting, clinical jaundice, or abdominal pain, an “unscheduled visit” should be made in which a directed clinical assessment and laboratory evaluations including creatinine, liver function tests, and complete blood count with differential are performed.

During regular business hours (8-5pm), the *UCSF Clinician Consultation Center PrEPline* (855-448-7737) is available to answer a range of questions for clinicians regarding PrEP management as well as the LA County DPH Provider Consultation line (213-368-7441). If patients develop symptoms of intolerance after hours, they will be primarily addressed by the CHS Duty Officer line (213)-288-8522 .

Patients with Abnormal Kidney Functions

Patients initiating PrEP for the first time should have their creatinine tested at baseline and after taking PrEP for 3 months and, if creatinine is stable, every 3-6 months after that. No patient receiving PrEP through SHCs should go longer than 6 months without having a creatinine test.

When checking kidney function, use the following online calculator for calculating CrCl: <http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault>

Before PrEP Initiation

Before PrEP initiation, if CrCl < 60, these patients should have the test repeated within 1-2 weeks. Assess the use of potentially nephrotoxic medications (NSAIDs, acyclovir, valacyclovir) and bodybuilding substances (creatine, protein drinks). If repeat CrCl is ≥ 60 , then patient may start PrEP. If not, the patient can be started on Descovy or Apretude. TelePrEP navigator will work with the patient to establish or re-establish care with PCP to have kidney function further evaluated.

After PrEP Initiation

If after initiation of PrEP, the CrCl < 60, PrEP should be discontinued immediately, and the creatinine should be repeated in 1 - 2 weeks. If the CrCl is ≥ 60 , may restart PrEP and check creatinine in 1 month.

If creatinine clearance is greater than 1.5x baseline (but CrCl is still ≥ 60), discuss with the patient to see if there are any other potential causes for the creatinine elevation (e.g., dehydration, bodybuilding supplements, new medications, NSAIDs) and repeat creatinine in 2 weeks. If creatinine elevation is sustained, patient can be started on Descovy or Apretude.

TelePrEP navigator will work with the patient to establish or re-establish care with PCP to have kidney function further evaluated.

During regular business hours, the *UCSF Clinician Consultation Center PrEPline (855-448-7737)* is available to answer a range of questions for clinicians regarding PrEP management.

Patients with Chronic/Active Hepatitis B Infection

The two drugs in oral PrEP, TDF, and FTC, are each active against both HIV infection and HBV infection and thus may prevent the development of significant liver disease by suppressing the replication of HBV. Therefore, patients with chronic HBV infection should be encouraged to receive PrEP in a primary care setting, where liver function can be monitored both during PrEP use and after any PrEP interruptions, and where comprehensive HBV management can occur. If oral PrEP is discontinued, then this can flare HBV.

Hepatitis B Virus Screening Serology Interpretation¹

HBsAg	Anti-HBc	Anti-HBs	IgM Anti-HBc	Interpretation	Action
Negative	Negative	Negative	—	Susceptible	Vaccinate
Negative	Positive	Positive	—	Immune (natural infection)	Document
Negative	Negative	Positive	—	Immune (prior vaccination)	Document
Positive	Positive	Negative	Negative	Chronic hepatitis B virus infection	Evaluate for treatment
Positive	Positive	Negative	Positive	Acute hepatitis B virus infection	Follow and evaluate for treatment
Negative	Positive	Negative	—	Unclear—might be: <ul style="list-style-type: none"> resolved infection (most common) false-positive anti-HBc; susceptible "low level" chronic infection resolving acute infection 	Case-by-case evaluation

Abbreviations: HBsAg, hepatitis B surface antigen; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody.

¹ Centers for Disease Control and Prevention, US Department of Health and Human Services: Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or other Nonoccupational Exposure to HIV, United States, 2016. Link: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

Hepatitis C Treatment

For patients with hepatitis C, referral to a primary care provider is an essential first step so that the patient can get additional testing (including genotyping and ultrasound) to help determine the need for referral and treatment. PrEP administration is not affected by Hepatitis C positive serology.

Women’s Health While on PrEP

Contraception

Per standard DPH clinic services procedure, women and persons who are able to get pregnant who need contraception can receive contraception in the SHCs PrEP is permitted during pregnancy by the FDA and perinatal antiretroviral treatment guidelines^{2,3}. No adverse effects have been found among infants exposed to TDF/FTC as part of a treatment regimen for pregnant women or pregnant persons with HIV or during breast(chest)feeding. However, the long-term safety of PrEP taken by women who are HIV negative after fetal (during pregnancy) or infant (during breast(chest)feeding) exposure is not yet determined., Patients who are pregnant or wish to become pregnant while taking PrEP will be started or continued on PrEP, but will be encouraged by our TelePrEP navigators to seek prenatal care and to further discuss with an OB/GYN.

Adolescent Minors

PrEP can be considered for adolescents (weight at least 35 kg or 77lb) who report sexual or injection drug use behaviors¹. In the ATTN 110 trial (age 18-22 years) and 113 trial (ages 15-17) for young MSM on Truvada (TDF/FTC), bone density changes were noted to be persistent 48 weeks after Truvada was stopped in the 15-19 age range versus those in the 20-22 age range¹. Due to this, Descovy (F/TAF) might be preferentially recommended to younger adolescent males¹.

Although adolescents can consent for HIV and STD screening and treatment, including PrEP, we think it necessary to refer these youth to clinics specializing in pediatric and adolescent medicine. Please refer youth under 18 years old who may be suitable for PrEP and/or other youth-friendly and LGBT-friendly medical services to Children’s Hospital LA or the Maternal, Child, and Adolescents Clinic at Los Angeles County – University of Southern California (see LAC PrEP Directory, available at www.gretprepla.com).

¹ Centers for Disease Control and Prevention, US Department of Health and Human Services: Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or other Nonoccupational Exposure to HIV, United States, 2016. Link: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

Mental Health Referral

Ask patients about their health insurance status. If they are insured, their insurance likely provides some degree of mental health coverage, and their insurance card will include a number for them to call (which may be noted as behavioral health).

For other cases, including uninsured patients, call the LA County Department of Mental Health's Access Center, available 24/7 at 1-800-854-7771 (Website: <https://dmh.lacounty.gov/get-help-now/>).

Substance Use Treatment Referral

Ask patients about their health insurance status. If they are insured, their insurance likely provides some degree of substance use treatment coverage, and their insurance card will include a number for them to call (which may be noted as behavioral health).

For other cases, including uninsured patients, call LA County's Substance Abuse Prevention and Control Program's Number (844)-804-7500 and can find additional resources at <https://sapccis.ph.lacounty.gov/sbat/>

Adherence Counseling

Patients should be asked about adherence during each visit over the past four days. Regardless of the number of missed doses, the provider should first encourage the patient about the doses they did to remember to take (strengths-based approach) prior to asking additional questions about missed doses. Below is an example of this conversation:

Provider: Mr. Roberts, how many doses of PrEP have you missed in the past week?
Patient: I think I may have missed two doses last week.
Provider: So, you were able to take 5 doses over the past week. That’s definitely to be commended. Life happens, which can make it difficult to remember to take medication sometimes. How were you able to remember to take those doses?
Patient: I took the pill with breakfast each morning during the week, but on the weekends, I wake up much later and sometimes miss breakfast altogether.
Provider: I see, so the weekends are when you forget because of a change in your routine. How do you think you might be able to remember? ***
Patient: I will try setting an alarm on my phone.
Provider: Sounds good, I’ll check in with you again at our next visit.

Alternatively, the provider could offer recommendations of ways to remember, but allowing the patient to brainstorm ways to address the problem may increase “buy-in” through their own idea generation. Adherence plans should be a joint decision between providers and patients, ensuring that the plan fits into the patient’s everyday way of living.

Broken Appointments

“Broken appointments” may take the form of the following:

- Patient misses any follow-up appointments and is unable to be reached for rescheduling.
- Patient does not pick up medications from a dispensary.
- Patient does not complete the required lab testing within 2 weeks of ordering.

For patients who meet one of the criteria above

- PrEP clinic staff to check-in, reschedule, and remind patients to obtain labs or medications or come in for their scheduled appointment.
- If a patient missed an appointment, ask them to come in for laboratory testing to be performed before their next appointment (if possible) to reduce delays in medication refill.
- Oral PrEP: One 30-day supply will be dispensed in the absence of labs or appointments, but if the patient fails to complete the scheduled task within 6 weeks, no additional refills will be dispensed.
- LAI PrEP: Please refer to LAI Missed Doses section to schedule patient

Section 4: Charting



Forms

All patients seen for PrEP services should have the following forms completed:

PrEP-PEP Ad-Hoc Form – Nursing – complete at every visit

The screenshot shows a web-based medical charting interface. The title bar reads 'PrEP-PEP Nursing - ZZZZTEST, ADULTPUMPSEVENTEEN'. The main content area is titled 'Pre Exposure Prophylaxis (PrEP)/Post Exposure Prophylaxis (PEP) History'. At the top, it shows the date '10/17/2018' and time '1844 PDT', and the provider 'By: TEST Jr, Physician - Amb'. The form is divided into two columns of questions. The left column includes: 'Has client ever taken PrEP?' (radio buttons for Yes/No), 'How many times has the patient taken PrEP?' (text input), 'Is patient interested in taking PrEP?' (radio buttons for Yes/No), 'If not interested in PrEP, why not?' (checkboxes for Don't need, Don't know about it, Concern about other's judgement, Afraid of side effects, Other), 'How was PrEP administered?' (radio buttons for Prescribed, Dispensed, No), and 'How did you find out about PrEP?' (checkboxes for PrEP Advertisement, Social media, Community event, Online Dating app, Friend/word of mouth, STD Clinic). The right column includes: 'Has client ever taken PEP?' (radio buttons for Yes/No), 'How many times has the patient taken PEP?' (text input), 'Is patient interested in taking PEP?' (radio buttons for Yes/No), 'If not interested in PEP, why not?' (checkboxes for Don't need, Don't know about it, Concern about other's judgement, Afraid of side effects, Other), and 'Was PrEP discussed with any partner?' (radio buttons for Some, All, None).

PrEP Ad-Hoc Form – Provider – complete at every visit

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

*Performed on: 10/17/2018 1846 PDT

PrEP Contraindications/Counseling

Possible Contraindication Checklist:

	Yes	No
Signs of acute HIV	<input type="checkbox"/>	<input type="checkbox"/>
History of Liver Disease	<input type="checkbox"/>	<input type="checkbox"/>
History of Kidney Disease	<input type="checkbox"/>	<input type="checkbox"/>
Pregnant?	<input type="checkbox"/>	<input type="checkbox"/>

PrEP Counseling Checklist:

- Labs reviewed
- Vaccination history reviewed
- Awareness of Acute HIV Infection (AHI) symptoms and plan
- Importance of PrEP adherence
- Potential risk-side effect of PrEP
- Plan for follow up visits and labs
- PrEP clinic discontinuation procedures

Reminder: Complete Clinic intake on this visit unless completed within the last 4 weeks

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

*Performed on: 10/17/2018 1846 PDT

Transition to Primary Care Provider (PCP)

Referred:

- PCP for PrEP
- PrEP "Center Of Excellence"

Reason for not referred:

- Uncomfortable with PCP
- No PCP established
- PCP will not prescribe
- Uninsured
- Discontinued use
- DHSP approved

Reminder: All patients should be transitioned to PCP or Center of Excellence within 8 weeks

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

*Performed on: 10/17/2018 1846 PDT

PrEP Contraindications
PrEP Transition
PrEP Treatment

PrEP Treatment

Date of Last PrEP Use:

Place Order: "Clinic Follow Up"

Side Effects

In the last 7 days, how many days did client take PrEP medication? __dose(s) out 7 doses

How many pills left since last visit? __pill(s)

Creatinine Clearance

Creatinine Clearance Date

Notes

Section 5: On the Horizon – Advances in PrEP Delivery



Advances on the Horizons: Long-Acting Subcutaneous Injectable PrEP: Lenacapravir

Lenacapravir, an capsid inhibitor that is currently used as a treatment option for multi-drug resistant HIV, has been studied for use as PrEP injectable monotherapy. Lenacapravir would be administered every 6 months as a subcutaneous injection. This is in contrast to cabotegravir, which is an intramuscular injection that is administered every 2 months. Information regarding the PURPOSE studies are here: <https://www.purposestudies.com/>

Section 6: Additional Biomedical Prevention Strategies



Doxycycline as post-exposure prophylaxis for bacterial STIs (DoxyPEP)

Studies have shown that taking Doxycycline as post-exposure prophylaxis (DoxyPEP) reduces the changes of getting syphilis and chlamydia by about two-thirds, especially for MSM and TGW.

Who can DoxyPEP be given to: Doxycycline can be administered to patients (12 years of age and older) who are at high-risk of STD acquisition for their personal use.

- Within the context of DoxyPEP, high-risk is defined as MSM or TGW who have had ≥ 1 bacterial STI in the past 12 months or patients who request DoxyPEP.
- Patients that can become pregnant should be counselled regarding pregnancy intention, offered family planning services, and informed that doxycycline is contraindicated during pregnancy

Labs and Testing: All patients requested DoxyPEP must first be tested for gonorrhea, chlamydia, syphilis, and HIV (unless patient was previously diagnosed or living with HIV). Gonorrhea and chlamydia screening will be done at all anatomic sites of exposure. Syphilis and HIV screening will be done on day 1 of medication dispensation and at the time of 30-day refill.

DoxyPEP prescription: Two 100mg of doxycycline should ideally be taken within 24 hours, but no later than 72 hours after condomless sex. If the patient has sex again within 24 hours of taking doxycycline, then the patient would need to take another 100mg doxycycline dose after your last dose. Patient should not take more than 200mg doxycycline every 24 hours.

Patient Instructions: DoxyPEP prescription medication information as noted above. Provider will educate patient on DoxyPEP and that patient must await results of STD testing prior to using medication to prevent ineffective treatment of the STD or risk of resistance. In addition, patient would need to take medication with food to avoid stomach upset (nausea, vomiting, diarrhea). Patient should not lay down for at least 30 minutes after taking doxycycline to avoid irritation and esophageal ulceration. Lastly, patients should avoid dairy products, calcium, anatacids, or multivitamins 2 hours before or after taking doxycycline.

Clinic Specific DoxyPEP Workflow

Business Office: Register patient in ORCHID per protocol

Nursing: Complete sexual health intake form per protocol. If patient was assigned to nursing as Express clinic patient, but patient is requesting DoxyPEP, then patient's appointment will be converted to provider visit

Provider: Review Sexual Health Intake Ad Hoc Form and confirm that patient is not having STI symptoms. Provider will then provide labs, prescription, and patient instructions as noted above.

- ORCHID Order: Doxycycline 100mg pO 2 tabs within 24-72 hours of sexual intercourse as needed QTY: 50 tabs using ICD-10 code, Z20.2 "Contact with and exposure to infections with a predominantly sexual mode of transmission".

LA County Resources



Division of HIV and STD Programs (Website)

Visit the Division of HIV and STD Programs (DHSP) website at www.publichealth.lacounty.gov/dhsp/ for program updates, health education materials, resources, and information on HIV, STDs, and PrEP/PEP.

For You

This section is for patients/clients. They can find information on HIV and the most common STDs and associated diseases, including HIV and STD prevention information, frequently asked questions, help to talk to partners about HIV and STDs, information by population, information by disease, and more.

<http://publichealth.lacounty.gov/dhsp/InfoForYou.htm>

For Health Care Providers

In this section, health care providers can find information on clinical practice alerts, health service alerts, and links that are designed to be helpful in the care and treatment of your patients.

<http://publichealth.lacounty.gov/dhsp/InfoForProviders.htm>

For DPH Sexual Health Clinics

In this section, staff can find information and resources for the Los Angeles County Department of Public Health Sexual Health Services. Additionally, if you want to receive DHSP updates and access presentations/CMEs, please [click here to join our DHSP HIV/STD Clinical Updates Microsoft Teams Channel](#) or email contacts on the following link.

<http://publichealth.lacounty.gov/dhsp/DPHSexualHealthServices.htm>

PrEP and PEP

In this section, health care providers and patients can find helpful information and resources pertaining to PrEP and PEP.

<http://publichealth.lacounty.gov/dhsp/PEP-PrEP.htm>

DHSP Health Education Library

The DHSP Health Education Library is a central hub for DHSP health education materials and resources that are helpful for understanding a variety of HIV/STD topics. Materials and resources are categorized by topics.

<http://publichealth.lacounty.gov/dhsp/HealthEducationLibrary.htm>

Get Protected LA (Website)

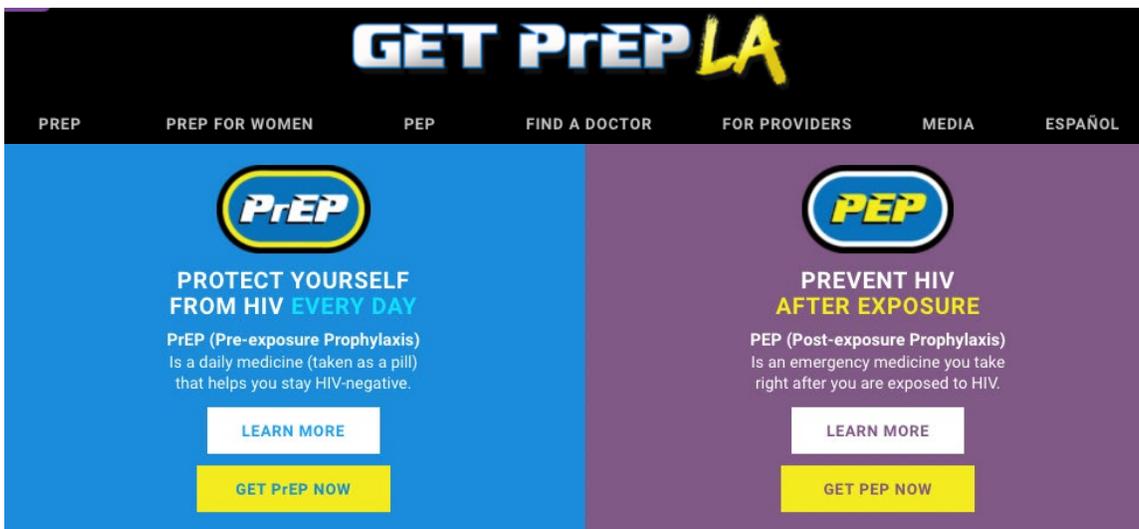
Visit [GetProtectedLA.com](https://www.getprotectedla.com) for more information, services, and resources on HIV and STDs.



Get PrEP LA (Website)

Visit [GetPrEPLA.com](https://www.getprepla.com) for more information on PrEP and PEP.

For questions or concerns regarding PrEP and PEP, please email prepinfo@ph.lacounty.gov or call (844) YEA-PREP.



Rapid and Ready Program (Treatment as Prevention)

Background

In Los Angeles County (LAC) there are approximately 53,599 persons (adult and pediatric cases) living with HIV (PLWH) in LAC as of year-end 2022. A Plan for America (EHE) is a national initiative which focuses on four key pillars of interventions (Diagnose, Treat, Prevent, and Respond) designed to help us reach the goal of reducing new HIV transmissions and acquisitions in the United States by 75 percent in five years (by 2025) and by 90 percent in ten years (by 2030). The EHE Treatment Pillar focuses on treating people rapidly and effectively and includes a linkage to care indicator to measure progress: Increase the proportion of people diagnosed with HIV who are linked to HIV care within one month of diagnosis to 95%.

While linkage to care data in LAC demonstrates increasing rates over the past 10 years, improvement is still needed to reach the EHE goal of 95%. In 2019, only 77% of persons who were newly diagnosed with HIV were linked to HIV care within 1 month, and when looking at linkage rates within 1 week, we see only 54% reaching that goal.

In response to our local data and as part of Los Angeles County's EHE plan, LAC's Department of Public Health Division of HIV and STD Programs (DHSP) developed a key strategy for rapid linkage to care and antiretroviral therapy (ART) known as the Rapid and Ready Program (RRP). RRP is designed to promote and support linkage to care within 7 days of a positive HIV test or for persons who are ready to reengage in care. With an overarching objective of reducing treatment delays, DHSP aims to reduce HIV transmission by helping people living with HIV achieve an undetectable viral load so they cannot transmit HIV through sex, also known as undetectable equals untransmittable or "U=U."

Program Overview

RRP addresses clinic and client-levels factors needed to create an environment for sustained rapid services. At the clinic-level, a network of Rapid Treatment Hubs that provide appointments within two days of referral and ART same-day has been established (http://publichealth.lacounty.gov/dhsp/RapidAndReadyProgram_ActionKit.htm). To support clients, RRP has formed a rapid navigator team who specialize in linking clients to Rapid Treatment Hubs and other needed support services.

Referrals from the Department of Public Health CS/CFS

CS/CFS referrals to the RRP Navigation Team can be made through the toll-free warmline at 833-351-2298. Referrals can be made either by providers or by clients self-referring themselves. Alternatively, an email can be sent to the Navigation Team's shared email at rapid@ph.lacounty.gov.

The information below is required, and a representative will call the client once reviewed.

1. Staff name, agency name, and contact number
2. First and last name of the client
3. Client date of birth
4. Client phone number
5. Date of test
6. Date of results were disclosed (A result disclosure must be performed prior to a referral being made unless authorization is obtained)



Need to see an HIV Provider?
Call the Rapid and Ready Navigation Team
833-351-2298



Ending
the
HIV
Epidemic

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