Pre-exposure prophylaxis (PrEP) is medication that when used correctly can reduce the risk of HIV through sexual transmission by 99% and can also prevent HIV transmission through injection drug use (USPSTF Grade A). PrEP is an important component of reproductive healthcare. The CDC recommends that healthcare providers discuss PrEP with all patients, at least once during their lifetime. Patients seeking abortion, family planning, and other reproductive healthcare may, in particular, benefit from PrEP.

This brief guide will help you start patients on PrEP on the same day as seeking abortion or other family planning care. For those abortion and family planning settings not equipped to provide *ongoing* PrEP monitoring and prescribing, PrEP can be started or prescribed same-day with a plan for the patient to follow-up with a clinical setting that provides ongoing PrEP care. PrEP clinics and providers for initiation and/or follow-up care can be found at preplocator.org.

For women and those at risk of acquiring HIV through receptive vaginal/front sex, there are currently two FDA approved PrEP options: a daily pill FTC/TDF (brand name Truvada®) and an injectable long-acting Cabotegravir (LA-CAB; brand name Apretude®). (See below) Of note, FTC/TAF (brand name Descovy®) has not yet been evaluated for women and those at risk of acquiring HIV through receptive vaginal/front sex.

Step 1: Inform all patients about HIV prevention options

Offer HIV testing to all patients attending an abortion or family planning visit. Inform all patients about HIV prevention options, including PrEP. HIV-negative individuals, including adolescents, who may benefit from PrEP include:

- People who ask for PrEP.
- People with HIV-positive partners.
- People with sexual exposures including: condomless vaginal and/or anal sex, multiple sex partners, sex partners at high risk for HIV, or transactional sex (such as sex for money, drugs or housing).
- People who have had a bacterial sexually transmitted infection (STI) within the past year.
- People who inject drugs (PWID) and people who use stimulants (e.g. methamphetamines) during sex.

Step 2: Discuss PrEP with your patient

Be present and listen. Ask about interest in and readiness for PrEP:

- What do you know about PrEP? Do you know anyone on PrEP?
- What makes you want to start PrEP? What do you hope PrEP will do for you?
- What barriers do you foresee? How long do you foresee being on PrEP?
- Do you prefer taking a pill once a day or having an injection every 2 months?

Let them know what to expect and about the potential benefits and side effects of PrEP. Important points include to include in discussion are:

Adherence	For oral PrEP, adherence is correlated with higher effectiveness. Tailor adherence strategies to patient needs and lifestyle (pillbox, phone or online reminders, cell phone alarms, etc.). Many people who inject drugs can adhere to PrEP. • For vaginal/front exposures, detectable drug blood levels equivalent to 6-7 doses/week are associated with a very high level of protection. For those who anticipate adherence challenges with daily oral PrEP, injectable Cabotegravir may be a preferred option.
Time to protection	To achieve adequate levels in cervico-vaginal tissue, it takes about 20 daily doses of FTC/TDF (Truvada®) and an estimated 7 days after the first LA-CAB (Apretude®) injection.

Risk of Resistance	Resistance to HIV medications can occur if acute HIV is not identified quickly while on PrEP. A negative HIV test result should be documented within 7 days before initiating PrEP and every 3 months thereafter. Please counsel the patient to report immediately to clinic if they develop symptoms compatible with acute HIV infection such as fever with sore throat, rash, or headache.
Potential side effects	PrEP is very well-tolerated. The specific side effect profile differs for oral and injectable PrEP. See below.

Step 3: Take a medical, sexual, substance use history and review of symptoms

Check for:

- HIV exposures in the prior 72 hours; if present, offer post-exposure prophylaxis (PEP): ebgtz.org/resource/pep-guide.
- Recent symptoms of a mono-like illness (fever with sore throat, rash, or headache): if present, test for acute HIV (order an HIVRNA PCR viral load and an HIV 4th generation Ag/Ab test) and consider deferring PrEP until test results are back.
- Any history of renal disease, osteoporosis, which impacts which PrEP agent is selected.
- Willingness and ability to take daily oral PrEP if that is the option chosen.
- Willingness and ability to return for regular appointments and labs while taking PrEP. If barriers are identified, we recommend still prescribing PrEP and also referring the patient to social work, patient navigation, or other programs that can facilitate transportation, etc.

Step 4: Using an informed free-choice model to help your patient select a PrEP medication

PrEP medication	**Oral FTC/TDF (Truvada®)** Tenofovir disoproxil fumarate 300mg + Emtricitabine 200mg 	**Injectable LA-CAB (Apretude®)** Injectable Long-Acting Cabotegravir 600mg=3mL 
Indications	FTC/TDF (Truvada®) is approved for use for all adults and adolescents ≥35 kg with indications for PrEP.	LA-CAB (Apretude®) is approved for use for all adults and adolescents ≥35 kg with indications for PrEP. LA-CAB (Apretude®) may be helpful for those: • With problems taking oral PrEP. • Who prefer getting a shot every 2 months. • Who have serious kidney disease.
Contraindications	• Known HIV infection. • Chronic kidney disease with eGFR <60 ml/min. • Concurrent use of adefovir.	• Known HIV infection. • Previous hypersensitivity reaction to cabotegravir. • Concurrent use of carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and or rifapentine. • While not an absolute contraindication, LA-CAB (Apretude®) has not been studied during pregnancy or lactation.
Dosing	1 pill once daily. *Of note, "on-demand" 2-1-1 dosing has not been studied among, and is not recommended for, women or those at risk for HIV acquisition via receptive vaginal/front intercourse.*	**Loading doses:** 2 injections 4 weeks apart followed by… **Maintenance doses:** injection every 8 weeks. **Optional oral lead-in to assess tolerability:** Oral cabotegravir 30 mg by mouth once daily for 28

		days, followed by injectable CAB within 3 days of ending oral lead-in dosing. Injection technique found on page 41 of the package insert.
Side effects	Generally safe and well tolerated • 1/10 people experience headache and/or abdominal discomfort, which usually resolve in a few weeks. • 1/100 people experience small decrease in eGFR, which improves upon discontinuation of FTC/TDF. • Slightly decreased bone density, but no increased risk of fractures.	Generally safe and well tolerated. • Injection site reactions (pain, redness, swelling), which generally improves with subsequent injections. • Headache, fever, fatigue, nausea, back pain, diarrhea, myalgia, and rash.
Other notes	Estimated GFR or CrCl by serum labs should be ≥60 ml/min (Cockcroft-Gault) to safely use FTC/TDF (Truvada®).	The randomized clinical trial HPTN 084 found a 90% lower incidence of HIV among cis-women on LA-CAB (Apretude®) compared to FTC/TDF (Truvada®) tablets, likely related to greater adherence.

Learn more about informed free-choice decision-making in healthcare HERE.

Step 5: Obtain baseline labs

HIV antibody test **OR** **HIV antibody + HIV RNA PCR test**	All patients need a documented negative HIV antibody test (ideally a 4th generation Ag/Ab) within a week of starting PrEP. This testing may be point-of-care or laboratory-based though oral HIV antibody testing should not be used to determine PrEP eligibility. Indications for obtaining both an HIV antibody test and HIV RNA PCR: • Patients who report a possible HIV exposure in the last month. • Patients currently taking or who have taken oral PrEP in last 3 months or injectable PrEP in the last 12 months. • Patients with acute HIV symptoms. Consider deferring PrEP until acute HIV has been ruled out with a negative HIV RNA PCR.
Serum creatinine (for FTC/TDF only)	Estimated GFR or CrCl by serum labs should be ≥60 ml/min (Cockcroft-Gault) to safely use FTC/TDF (Truvada®). An online calculator can be found here: tinyurl.com/CrClcalculator.
Hepatitis B surface antigen (HBsAg) (for FTC/TDF only)	FTC/TDF (Truvada®) is active against hepatitis B virus (HBV). Patients with chronic HBV can use PrEP but should have liver function tests monitored regularly during PrEP use and after discontinuing PrEP; hepatitis can flare if PrEP is discontinued. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
Hepatitis C (HCV) antibody	Among PWID and others with possible exposure, including people who have anal sex.
STI (based on sexual exposures)	Baseline chlamydia, gonorrhea, and syphilis screening: cervico/vaginal, rectal, and/or pharyngeal based on reported exposure routes. Consider using self- collected swabs for GC/CT testing. Consider offering the HPV, hepatitis A virus (HAV), and hepatis B (HBV) vaccines if not previously vaccinated.
Pregnancy test	People who can become pregnant (reproductive-age cisgender women, some transgender men, and non-binary people) should receive a pregnancy test and have contraception plans reviewed. In patients trying to conceive, PrEP should be coordinated with prenatal care with attention to the patient's reproductive and breastfeeding plans. Descovy® is NOT approved for use as PrEP in this population. Perinatal HIV/AIDS consultation is available at 888-448-8765 or online at https://nccc.ucsf.edu.

Step 6: Initiate PrEP

Same-day PrEP start or prescriptions are encouraged when possible. Analogous to initiating same-day contraception, we strongly encourage dispensing a 30-day supply of oral PrEP, giving the initiation injection of LA-CAB (Apretude®), or writing a prescription and starting PrEP on the same day a patient comes in for consultation when:

- The patient has a negative HIV test within the last 1 week and no HIV exposures since this test or a negative rapid HIV test on the day of consultation,
- All other laboratory testing is obtained that day (even if results are not yet available), and
- The patient has no symptoms of acute HIV infection.

Same-day PrEP initiation is not appropriate for:

- Patients with ambivalence about starting PrEP.
- Patients for whom blood cannot be drawn for laboratory testing.
- Patients with signs/symptoms and sexual history concerning for acute HIV infection.
- For oral PrEP: Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes) and unknown renal function.
- Patients who do not have a confirmed means of contact should laboratory testing indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction for oral PrEP).

To transition from PEP to PrEP, check an HIV 4th gen Ag/Ab test while on week 4 of PEP and prescribe PrEP so the patient can start PrEP the day after PEP is completed. Confirm that the HIV testing done during week 4 of PEP is negative.

- Provide adherence counseling and anticipatory guidance about common side effects.
- Discuss patient strategies for daily adherence.
- Counsel patients on risk reduction using condoms with PrEP to decrease transmission of STIs.

Step 7: On-going monitoring

	Oral FTC/TDF (Truvada®)	Injectable LA-CAB (Apretude®)
Every 2 months		*At <u>every</u> injection visit:* • HIV test (HIV RNA PCR 'viral load') • Assess for symptoms of acute HIV • STI testing as guided by symptoms and sexual activity
Every 3 months	• HIV test (ideally 4th gen Ag/Ab) • Assess for symptoms of acute HIV • Assess for adherence • STI testing as guided by symptoms and sexual activity • Refill a 90-day supply (until next HIV test)	
Every 4 months		*At <u>every other</u> injection visit:* • STI screening as guided by symptoms and sexual activity • Pregnancy testing as guided by sexual activity
Every 6 months	• eCrCl for persons age ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • STI testing as guided by symptoms and sexual activity	• STI testing as guided by symptoms and sexual activity
Every 12 months	• eCrCl for persons age <50 years or who have an eCrCl ≥90 ml/min at PrEP initiation • Chlamydia screening • Gonorrhea, Syphilis, and HCV screening as indicated by local guidelines	• Chlamydia screening • Gonorrhea, Syphilis, and HCV screening as indicated by local guidelines

Step 8: Providing ongoing support for patients using PrEP

Many abortion clinics do not provide ongoing follow-up after abortions. A key component of starting/prescribing PrEP is establishing a follow-up plan for laboratory monitoring, adherence assessment, and ongoing prescriptions. Consider establishing a relationship with providers in your community who are willing to accept a warm handoff once PrEP has been prescribed by you/in your clinical setting. Local PrEP providers can be found here. Telehealth is an acceptable option for follow-up if the patient can continue to access necessary laboratory testing.

Step 9: What if my patient tests positive for HIV while on PrEP?

a. Discontinue PrEP to avoid development of HIV resistance.
b. Start patient on HIV antiretroviral treatment as soon as possible in accordance with HIV Treatment Guidelines and/or facilitate a warm hand-off referral to an HIV provider immediately. A directory of HIV care providers can be found on the HRSA website.
c. For questions and support, call the National HIV Clinicians Consultation Center: 800-933-4313.
d. Order HIV genotype and document results.

Step 10: PrEP coverage options

Connecting patients with PrEP navigation services can help them address financial barriers to PrEP.
This diagram helps patients figure out how to pay for PrEP.

Insured patients

- Private insurers are required to cover PrEP/PEP medications and related medical services, and most plans in California now pay for PrEP with $0 cost sharing.
- PrEP should not be subject to prior authorization by California-based insurance plans.
  - Adolescents covered on their parents' plan can keep their info confidential in California by signing up at myhealthmyinfo.org.
- Within California, for Medi-Cal prescriptions, we recommend writing a note to the pharmacy to "bill the Medi-Cal HIV carve-out directly and not the managed-care plan" to ensure Medi-Cal coverage.
  - For adolescents, the Medi-Cal Minor Consent Program can help pay for PrEP/PEP and keep the services confidential.
- **ICD-10 codes** for PrEP include:
  - Z20.6: Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
  - Z20.2: Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
  - Z71.7: Human Immunodeficiency Virus (HIV) counseling
- If patient needs help with co-pays, the Gilead co-pay assistance program can provide assistance for FTC/TDF (Truvada®) (877-505-6986) and the ViiV Savings Program (844-588-3288) can provide assistance for Cabotegravir.
- The California PrEP Assistance Program (PrEP-AP) helps low income [≤500% Federal Poverty Line (FPL)] insured patients pay for PrEP-related out-of-pocket costs, such as medical visits and labs, and also assists with FTC/TDF (Truvada®) co-pays after the Gilead benefit is exhausted.

Uninsured patients

- Multiple generics for FTC/TDF are now available for low cost (<$30/month)
- The **Gilead Advancing Access** PrEP medication assistance program will provide monthly FTC/TDF (Truvada®) deliveries to the patient or clinic at no cost for those without prescription coverage and who meet income guidelines (≤500% FPL).
  - Call 800-226-2056 for inquiries or to apply by phone, Monday-Friday, 6am-5pm PST.
  - Fax the completed application and proof of income to 855-330-5478.
  - If approved, one bottle (30-day supply) will be available for pickup at any non-Kaiser pharmacy. For pickup, provide an ID, bin, group, or PCN number (provided by Gilead). Refills can be coordinated with the pharmacy.
  - Alternatively, medication bottles may also be shipped to a clinic in 3-14 days. A Gilead representative will call the provider before the 2nd bottle is sent to confirm refill if continuing to ship to clinic.
  - Patients must re-apply (i.e. resubmit proof of eligibility) every 12 months.
  - U.S. and undocumented residents are eligible. Social security numbers are not required. Proofs of income include: W2, 1040 tax return, 2 pay stubs from the last 90 days or letter stating monthly income.
  - The letter stating monthly income should include the residence address and must be signed and dated but does not need to be notarized.
- The **ViiV Patient Assistance Program** offers free Cabotegravir for those patients who qualify.

- The **Ending the HIV Epidemic: Ready, Set, PrEP program** (getyourprep.com) will provide monthly FTC/TDF (Truvada®) deliveries to the patient or clinic at no cost for those without prescription coverage regardless of income for up to 200,000 patients per year. This is a nationwide program, including tribal lands and territories Patients must provide proof of lack of prescription coverage, a recent negative HIV test result, and a current prescription for PrEP.
- The **California PrEP-AP program** serves uninsured low-income patients (≤500% FPL) as a payer of last resort for PrEP-related medical costs (e.g. labs, visits, STI treatment) and must be used in conjunction with the Gilead Patient Assistance Program. Patients are not required to use the Ready, Set PrEP program before enrolling in CA PrEP-AP.
- For PEP, call 844-421-7050 Monday-Friday 8am-5pm for immediate enrollment.

Have questions?

The National HIV PrEPLine for clinicians provides guidance on PrEP: 855-448-7737.

Go to PleasePrEPMe for a location-responsive California PrEP provider directory, and many resource pages including for patients, providers, youth, trans and non-trans women: pleaseprepme.org.

Further information about PrEP can be found at:

- getSFcba PrEP Program Toolkit: **https://getsfcba.org/resources/prep-program-toolkit/.**
- CDC website: **cdc.gov/hiv/risk/prep/index.html**.
- San Francisco City Clinic's website: **sfcityclinic.org/services/prep.asp**.

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getSFcba, the CBA program of the San Francisco Department of Public Health, is funded by the US Centers for Disease Control and Prevention (CDC) under Funding Opportunity

Announcement 19-1904. The creation of this resource was supported by Cooperative Agreement Number 5U65PS004411-02. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.

The Pacific AETC is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $3,887,700.00. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

Trade Name Disclosure Statement
Funding for this resource was made possible by 5 U1OHA29292-08-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.