

## PrEP Navigation Services

### Protocol for providing pre-exposure prophylaxis (PrEP) for HIV prevention at San Francisco City Clinic

#### Description

PrEP can be an effective part of a comprehensive HIV prevention package for HIV-negative individuals. San Francisco City Clinic (SFCC) patients who are at ongoing risk for HIV may benefit from taking PrEP. Taking PrEP requires regular follow-up with a healthcare provider. Currently, Truvada is the only medication that is FDA-approved for PrEP. SFCC provides PrEP consultation, education and navigation, and will initiate PrEP and provide follow-up for patients who meet one of these criteria:

1. The patient is uninsured and qualifies for the Gilead Advancing Access Program (MAP).
2. The patient has private insurance or Medi-Cal but is unable to access PrEP because:
  - a. they do not yet have a primary care provider (PCP);
  - b. they have a PCP who has refused to prescribe PrEP;
  - c. they have a PCP, but are uncomfortable discussing sexual health with that provider; and/or
  - d. they have difficulty getting regular appointments with their PCP or are unable to afford copayments for office visits or labs.

Note: Patients with Kaiser, VA, or Chinese Community Health Plan (CCHP) cannot access PrEP at City Clinic and must see their in-network providers for PrEP. From this point, the term “eligible private insurance” will be used in this protocol.

After initiating PrEP at SFCC, patients will be actively assisted with addressing whatever barriers prevent them from receiving PrEP in a primary care setting. This includes helping patients navigate the benefits system to access comprehensive health insurance, find a PCP who is knowledgeable about PrEP, and/or develop tools for communicating with their PCP about PrEP.

Items highlighted in yellow are recent changes to the protocol as of \_\_\_\_\_.

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## 1. **Initial consultation and establishing eligibility**

This section describes the first consultation with a patient at which a PrEP staff member will provide education on PrEP; assess HIV risk and desire/need for PrEP; discuss PrEP access and establish eligibility to receive PrEP at SFCC.

1. Any HIV-negative SFCC patient may be referred for PrEP consultation by a SFCC clinician or other SFCC staff based on the patient's interest in PrEP and their risk for contracting HIV. See *Appendix A* for risk guidelines.
2. A PrEP staff member will assess patient's HIV risk, insurance status, and any general health concerns that might prevent PrEP from being a suitable and safe intervention. The PrEP staff member will counsel the patient regarding the risks/benefits of PrEP, adherence, and possible side effects.
3. If the patient has Medi-Cal or eligible private insurance we can initiate PrEP immediately if the patient wants to do so (see 2. PrEP Initiation). Patients with private insurance should be encouraged at initiation to continue follow-up with their PCPs if able to do so. When there are barriers to that (patient has no PCP, delays in getting appointments, uncomfortable with PCP) we will continue to follow the patient until which time they can transfer care to a PCP. If there are contraindications to same-day PrEP initiation, the patient should return to clinic as soon as possible after all concerns are addressed. If the patient doesn't want to initiate the same day, patient should be encouraged to return to clinic as soon as possible. Patients with eligible private insurance should be given information for PrEP assistance programs: Gilead copay card, which provides \$7,200 of copay assistance yearly starting September 1, 2018 ([www.gileadcopay.com](http://www.gileadcopay.com) – minors cannot apply online but can do so by phone at 800-226-2056), PAN ([www.copays.org/diseases/hiv-aids-and-prevention](http://www.copays.org/diseases/hiv-aids-and-prevention)), and/or PAF ([www.copays.org](http://www.copays.org)). Refer to *Appendix B* for health insurance FAQs. All privately insured patients should be asked for their insurance card at the first visit, and a copy made to scan into EMR.
4. If the patient is uninsured or unable to access PrEP through a PCP, PrEP staff will explain the requirements for receiving PrEP at SFCC. Uninsured patients may be eligible to receive PrEP from SFCC through the Gilead MAP if they reside in the U.S. PrEP staff will complete and submit MAP application on patient's behalf. The application can be found here:

[https://services.gileadhiv.com/content/pdf/gilead\\_enrollment\\_form.pdf](https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf).

The application requires proof of income, usually in the form of the applicant's two most recent pay stubs (cannot be more than 90 days old), a recent tax return or a W2 form (cannot be more than 90 days old). If an applicant cannot supply any of the above, they may submit a statement of current income (statement must have a date and signature), though patients who have paystubs should be encouraged to try to furnish them during the same visit when they complete the application. If they cannot furnish paystubs before the end of the visit, assist

them with writing a statement of current income. If a patient has no income, the application should include information about how they are being supported. Gilead will also want to know why the applicant does not have health insurance and what the applicant's plan is for getting health insurance if eligible. All additional information submitted with the application can be recorded on an attachment to the application.

Gilead will generally approve applications for anyone who is uninsured and has a yearly income  $\leq$  \$60,700 (500% over the 2018 Federal poverty level). If a patient's MAP application is denied, a PrEP staff member will contact Gilead to discuss appealing the denial. Patients should be informed that, if approved, Gilead generally authorizes 12 months of free Truvada through the MAP at a time. If the patient requires additional assistance, they may have to reapply for the program. For patients who qualify for Medi-Cal, they will only be approved once in their lifetime while they continue to be eligible for Medi-Cal, and so should apply to Medi-Cal as soon as possible, even if approved for Gilead. For patients who qualify for Covered CA, they will receive an enrollment valid until December 31 of that calendar year, at which time they can re-enroll if they do not enroll in a Covered CA plan. Minors applying to the Gilead MAP should have a PrEP staff sign on their behalf as an "advocate," as Gilead will approve the coverage but does not accept signatures from minors.

Patients who are approved for the MAP will receive program identification numbers that will allow them to fill their Truvada prescription at a pharmacy at no charge.

When possible, complete the MAP application during consultation and have patient supply missing information as soon as possible. If the patient is approved, notify the patient and have the patient drop into City Clinic for an intake/initiation visit. Pharmacy ID information can be obtained by calling Advancing Access the day after the patient is approved for the MAP. If the PrEP navigator/counselor believes that the patient will be approved in less than 7 days, PrEP staff can conduct initiation procedures the same day. The patient will receive a prescription the same day, and the counselor will inform the patient that they will receive a text in several days with the ID number in order to then fill the prescription without having to return to the clinic again.

5. Uninsured patients should be provided information about Covered CA and Medi-Cal and encouraged to apply for insurance. Uninsured patients who are California residents and who earn  $\leq$  \$16,754 are likely eligible for Medi-Cal. San Francisco residents can apply through the Human Services Agency of San Francisco in person at 1440 Harrison Street (recommended) or online at [www.mybenefitscalwin.org](http://www.mybenefitscalwin.org). Residents of other counties should contact their local Medi-Cal office. Uninsured patients who are California residents and who earn  $\geq$  \$16,395 can purchase a plan on the health insurance exchange through Covered CA ([www.coveredca.com](http://www.coveredca.com)) during open enrollment periods or within 90 days of a qualifying life event. Patients purchasing a plan should be advised to contact the plan for information regarding the cost of Truvada as PrEP and should be instructed that cost sharing, copayments, and deductible vary significantly between plans. See *Appendix B* for FAQs and other information regarding Covered CA plans.
6. Patients who do not qualify for Medi-Cal or the Covered CA plans, may be eligible for Healthy San Francisco (HSF). The patient should contact Healthy San Francisco or visit [www.healthysanfrancisco.org](http://www.healthysanfrancisco.org). If patients are eligible for Healthy San Francisco, it is important for them to choose a medical home within the San Francisco Health Network

(SFHN). Medical homes outside of the SFHN may not cover PrEP. Pharmacy navigators at SFGH will assist patients who have HSF and a medical home within the SFHN to apply for the Gilead MAP. If they do not qualify for the MAP, HSF will provide PrEP on a sliding scale basis. Patients who have HSF and qualify for the Gilead MAP, but do not yet have a medical home can receive PrEP at SFCC. Patients who are eligible for HSF but who have not enrolled should be encouraged to do so.

7. If a patient qualifies to receive PrEP at SFCC, staff can proceed with the initiation process while the patient is here or by having the patient drop in to City Clinic during normal hours.
8. PrEP visits at SFCC are on a drop-in basis during normal hours. PrEP staff may decide to schedule an appointment for a patient who has an active PrEP navigation assignment or who for other life reasons needs some extra support in initiating and staying on PrEP.
9. PrEP staff will assess client insurance and eligibility at every PrEP visit. In the course of assisting clients in applying for benefits programs, under no circumstances will PrEP staff knowingly provide fraudulent information or counsel the client to provide fraudulent information in order to obtain benefits. If client is not able to access Truvada through a mix of insurance and benefits programs, PrEP staff will inform client that some patients with no other affordable options have purchased generic TDF/FTC from online, overseas-based pharmacies. Clients who elect this option will be offered clinical monitoring in SFCC's PrEP program and we will otherwise treat them as any other program participant. Advise the patient that it may take longer than 7 days to receive their medication if using an overseas pharmacy, and that we recommend re-testing if they do not start taking medication within 7 days of the HIV test. If PrEP staff provide information about generic TDF/FTC, they will provide the following website as the main source of information for clients to read:  
[iwantprepnw.co.uk](http://iwantprepnw.co.uk)
10. Occasionally a patient does not know their insurance, either because it recently changed or they simply forgot to bring their insurance card. In these instances, PrEP staff will pursue the following options in order maximize the ability to complete same-day PrEP initiation (or follow-up) procedures:
  - a. First: Obtain patient's verbal consent and then call either Walgreens specialty on 18th St with the patient's name, DOB, and SSN, to request an insurance check. Sometimes this can take an hour but it is usually is faster, sometimes instantaneous.
  - b. Second: If Walgreens does not find the current insurance, submit a Gilead application as a "Benefits investigation". This takes usually 2 business days, so same-day PrEP is not an option in this case. The outcome is a one-page fax that details insurance info including deductible and copays. To complete the request, complete the application as usual, but check the "Benefits Investigation" box at the top and attach a copy of the insurance card (front and back).
11. Occasionally, SFCC sees new or existing PrEP patients who recently switched to Kaiser insurance. In this case, patients should be counseled that they will be permitted to fill one month of Truvada at Kaiser's pharmacy off of the 3-month prescription we provide them. Subsequent refills will need to come from a Kaiser provider. In the case of these patients and when time in the clinic schedule permits, PrEP staff should offer the patient to make a phone

call together to Kaiser's PrEP line to complete the linkage and schedule the first appointment. At minimum, PrEP staff should provide patients with Kaiser SF's PrEP phone number and encourage them to call as soon as possible to establish PrEP care.

## 2. PrEP initiation visit

See *PrEP Intake Checklist* on exam room computers and in CCEMR/PrEP tab.

1. The PrEP clinician will conduct a medical history to assess whether or not the patient has any medical relative or absolute contraindications to PrEP, including history of kidney/liver disease, current or chronic hepatitis B, osteoporosis or other bone disease, or symptoms of acute HIV. Please consult SFCC medical director regarding any kidney, liver, bone disease, uncontrolled chronic diseases and/or medication interaction concerns. Use clinician discretion for safety of starting PrEP in patients with complicated medical conditions that require monitoring by a PCP. Consider more frequent monitoring if clinically indicated, e.g., in the setting of diabetes or uncontrolled hypertension. PrEP can be initiated without waiting for creatinine result unless there are circumstances in the patient's medical history that warrant waiting.
2. Clinician will assess for symptoms of acute HIV and if concerned about a recent HIV infection consider delaying PrEP initiation until all HIV window periods are closed with a negative HIV (RNA) result. If a patient reports a possible HIV exposure within the past 72 hours, the clinician should initiate PEP. PrEP navigation staff will work with PEP patients to make the transition to PrEP without a gap in treatment.
3. The clinician should take the patient's weight (pounds) to calculate creatinine clearance, and blood pressure. Patients should also have a complete STI screening if one has not been done within the previous three months.
4. Clinician will order the following tests for the patient: HIV rapid Ab & RNA tests (if patient has not had them within the past seven days), HCVAb rapid test (if patient has not had one in the past year), HBsAg test, and creatinine.

Additional optional testing: The clinician may use discretion in ordering additional tests, for example, liver function; metabolic panel; CBC; etc. Clinician should consult with PrEP coordinator or SFCC medical director for discretionary tests and requirements for timing of specimen collection and transport.

5. The patient must receive a nonreactive rapid HIV antibody result no more than seven days before Truvada is dispensed for the first time. See follow-up visit procedures (**Section 4**) for further HIV testing guidelines. If patient completes a PrEP initiation visit (including an HIV test) and then does not start taking PrEP within 7 days for any reason (e.g. delayed Gilead approval, busy schedule, etc.), PrEP staff should recommend patient return to clinic to repeat the HIV test before starting PrEP and explain that there are risks of partially treated HIV and Truvada-resistant HIV if take Truvada after unknowingly acquiring HIV. However, if the next step needed for the patient to be able to begin PrEP is to receive the Gilead ID, PrEP staff will provide the ID and not withhold it, pairing it with the recommendation to return to clinic for testing.
6. All specimens for lab tests are drawn at SFCC. See **Section 8** for further details.

7. Patients who have not been vaccinated for hepatitis A and B, meningococcal disease or HPV should be encouraged to begin the vaccination series at SFCC.
8. When there are no contraindications to initiating PrEP (see **Section 3** below), patients with private insurance or Medi-Cal can be given a 90-day prescription (no refills) at the intake appointment. (Truvada is billed by the pharmacy to FFS Medi-Cal and not to the patient's managed care plan, except Health Plan of San Mateo members, who must use the Alphascript specialty mail order pharmacy.) PrEP can be initiated without waiting for the HBsAg and creatinine results unless there are circumstances in the patient's medical history that warrant waiting. If patients have already been approved for the Gilead MAP, they can be given a 90-day prescription (no refills) along with the Gilead pharmacy ID information. In some cases due to clinical or counseling concerns, the clinician can write a 30-day prescription (no refills) and ask the patient to return to the clinic for a 30-day follow-up visit post-initiation.
9. All prescriptions for Truvada for PrEP should be written with ICD-10 code z20.6. Other ICD codes have led to billing issues.
10. In rare instances, PrEP staff may wish to advance patients Truvada pills if there is concern about missing doses and HIV risk. Please consult with PrEP Coordinator or a clinician before dispensing.
11. Review "The Basics" hand-out with the patient. Refer to package insert and CDC guidelines for details on possible changes to bone mineral density (BMD). Counsel patient on strategies to maintain bone health. See **Section 6** for messages on long-term side effects.
12. Condoms and risk reduction and medication adherence counseling should be provided to patient by either the clinician or other PrEP staff (see **Section 12**).
13. The PrEP clinician or counselor should conduct a psychosocial needs assessment on all patients and make referrals for counseling, case management, and/or other services, as needed.
14. PrEP counselor should perform pharmacy counseling as follows: Before concluding the visit, tell the patient the following: "We have seen people have an easier time filling prescriptions for PrEP at Walgreens than at other pharmacies. Would filling it at Walgreens work for you?"
  - a. If patient says **NO**, assure them they can fill it anywhere they want. Of course, this also will not work for Anthem BC Medi-Cal patients, who must use Safeway or CVS, nor for patients whose plans require a mail order pharmacy, or who need the type of help that only specialty pharmacies like Alto can provide. Therefore, do not offer Walgreens to those folks.
  - b. If patient says **YES**, tell the patient, "Great. Which Walgreens do you plan to fill this prescription at? When do you plan to go fill the prescription?" Then give patient the paper Rx.
  - c. Document the pharmacy location of preference in the counseling note for the visit in EMR.

15. PrEP counselor should provide basic PrEP education to all patients initiating PrEP by covering the following main talking points:

- a. If your plan to start PrEP does not go accordingly, or you stop, and have condomless sex or share needles, remember that there is a morning after pill for HIV called PrEP that lasts 28 days and is very effective. We offer it here, or you can get it at urgent care or emergency rooms. If you aren't sure whether you should come in for PrEP, just call us. We're happy to help.

### **3. Contraindications to initiating PrEP**

Most patients can be started on PrEP as soon as possible. However in some cases, PrEP staff/clinician may decide to delay PrEP initiation or to refer a patient to primary care for PrEP initiation. In all cases, PrEP clinicians and other staff will consider the patient's ongoing HIV risk with the benefits or risks of starting PrEP immediately.

1. If it is suspected that a patient might have acute HIV, PrEP should be delayed until we receive the most recent RNA result and/or we receive a RNA result or a Determine Ab/Ag result closing out a recent window of HIV risk. Window periods: 10 days for RNA; 21 days for Determine.
2. Patients who are suspected of having hepatitis B or who are known to be HBV+ may initiate PrEP at the clinician's discretion. Labs to include at intake if known HBV+: AST, ALT, HBsAg, Hepatitis B viral load (HBVL). Plan in either case will be for patient to transition to primary care ASAP. Patients with a positive HBsAg 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. Patients with chronic HBV or who receive a new HBV+ result and who have initiated PrEP should be counseled not to stop taking Truvada without consulting with their PCP.

#### **Hepatitis B Surface Antigen screening**

- HBsAg screening at intake visit. If positive, have patient return to clinic to check AST, ALT and HBVL (ARUP: Hep B virus DNA quant RT-PCR). If HBVL positive indicating active hepatitis B, patient should receive PrEP from PCP. If patient has started Truvada, instruct patient to continue taking it at least until meeting with PCP.
- Recent hepatitis B vaccination? Delay HBsAg testing until 4 weeks after vaccination to avoid false positive result. PrEP should not be delayed.
- If HBsAg positive and VL negative, consult with Medical Director. Patient should be referred to primary care for additional work-up. PrEP can be continued.

#### **Hepatitis C Antibody screening**

- All PrEP patients should be screened at initiation and yearly thereafter while on PrEP.
- Test patients using City Clinic rapid hepatitis C antibody test/protocol. If positive ab result, blood specimen is automatically sent to lab for VL testing. If positive HCV VL, patient should return to clinic for AST/ALT testing. Refer all patients with positive HCV ab or VL results for HCV navigation (see SFCC HCV Protocol).
- PrEP can be initiated or continued at City Clinic for patients with existing or new diagnosis of hepatitis C. Refer all patients to primary care for Hepatitis C

management/treatment; ok to continue PrEP at City Clinic until then. Consult with MD if questions.

#### 4. **Follow-up**

See *PrEP Follow-up Checklist* on exam room computers and in CCEMR/PrEP tab.

1. All patients initiating PrEP are seen on a quarterly basis. All patients will receive a two-week follow-up text post-initiation to confirm if they were able to fill the prescription, and to offer help with troubleshooting if not.. (See **Section 14** Retention.)
2. At follow-up visits at which patient is due to receive a new Truvada prescription, we can accept a negative HIV rapid antibody result within seven days of dispensing Truvada.
3. The PrEP clinician should assess patient for acute HIV or STI symptoms, possible side effects, order creatinine and HIV tests (rapid Ab and pooled RNA), and conduct STI screening at least every three months.
4. Patients initiating PrEP for the first time should have their creatinine tested after taking Truvada for three months and, if creatinine is stable every three-six months thereafter. No patient receiving PrEP through SFCC should go longer than six months without having a creatinine test. See **Section 7** below.
5. At follow-up visits, the clinician should write the prescription for 90 days for privately insured patients. For all other patients, write it for 30 days with 2 refills. In cases of patient travel, a prescription of up to 120 days can be written; do not prescribe > 120-day supply at a time. (See **Section 13 Travelers Protocol**.)
6. Offer condoms and provide risk reduction and medication adherence counseling to patient.
7. Conduct a psychosocial needs assessment, as needed, and make referrals for counseling, case management, and/or other services.
8. PrEP counselor should perform pharmacy counseling as follows: Before concluding the visit, ask the patient what pharmacy they are filling at, and whether there are any issues. Document the pharmacy in the counseling note for that visit in EMR, or document that there is “no change to pharmacy” since last visit. For patients with prior issues filling Rx’s such as losing the paper copy, offer: “I’d love to call in the Rx [to Walgreens, if allowable based on insurance] for you to help avoid any issues this time. What pharmacy location can I call it into? When do you plan to go pick it up?”
  - a. If patient declines to have Rx called in, give them the paper Rx and document in the EMR note that they declined.
  - b. If they accept, call in the Rx directly to the pharmacy they indicated. Document the pharmacy location as well as the fact that the Rx was called in, in the counseling note in EMR. Also, add a note to the “patient comments” box so that we know to call in future Rx’s as well.

9. PrEP counselor should provide basic PEP education to all patients at follow-up PrEP visits by covering the following main talking points:

a. If ever you have a gap in taking PrEP and have condomless sex or share needles, remember that there is a morning after pill for HIV called PEP that lasts 28 days and is very effective. We offer it here, or you can get it at urgent care or emergency rooms. If you aren't sure whether you should come in for PEP, just call us. We're happy to help.

10. All patients should receive a text/phone call/email roughly 14 days before our records show they will run out of medication, reminding them to return to SFCC for follow-up and to receive a new prescription. (See **Section 14** Retention.)

11. The clinic routinely receives requests from pharmacies and patients to authorize an Rx refill, even when the patient has not been seen in the past 3 months for a quarterly PrEP follow up visit. PrEP staff and clinicians should not authorize refills in this case, except as provided in **Section 13** PrEP Procedures for Travelers. In the event that a patient has a legitimate need for a new Rx between quarterly visits (e.g. they cannot remember what pharmacy they filled at previously and so they cannot retrieve the next refill; or their insurance changed since the last visit and now they require a switch to a mail order pharmacy, etc), PrEP staff will make every effort to assist the patient in transferring the Rx to the current pharmacy of choice. This assistance may include counseling the patient on techniques for transferring the Rx, or calling the pharmacy directly to sort out details. As a last resort, PrEP staff may call in a new Rx, but only after consulting with a clinician who deems it appropriate. PrEP staff will both enter the new Rx into the "Prescriptions" button on the CCEMR home page under the clinician's name, as well as enter a progress note explaining the circumstances for the Rx refill and name which clinician was consulted.

## **5. Managing gaps in pill taking**

### **1. Patient reports gap during phone call with counselor:**

When a patient has been off PrEP for  $\geq 7$  days and has had an HIV test within the past 3 months, the patient should be counseled to resume pill taking as soon as possible. The patient should be informed that if they had condomless anal or vaginal sex while off PrEP, they could have acquired HIV. If they report having such an exposure off PrEP, they should be invited to come in for an HIV test sooner than their next quarterly (ideally at least 7 days after the exposure to allow for the PVL window period).

If they report condomless anal sex or receptive vaginal/frontal sex in the past 72 hours *and* have been off PrEP for  $\geq 7$  days, they should be advised to resume Truvada ASAP and come in for evaluation and addition of a third drug for nPEP.

In either case, the patient should be counseled about barriers to adherence and provided suggestions/tools for optimizing adherence.

### **2. Patient reports gap while at clinic visit:**

Patients off PrEP for more than one week (and those who report non-daily adherence) should have visit follow-up procedures per usual protocol for a quarterly visit, and should be counseled about barriers to adherence and provided a pill box, etc.

## 6. **Short- and long-term side effects**

Truvada has been used in HIV-positive patients for over 15 years. It was FDA approved for PrEP in July 2012. Data show that Truvada is safe and well-tolerated. The following side effects should be discussed with patients:

1. **Start-up syndrome**: Some people may experience nausea, gas or bloating, soft stools or diarrhea, headaches, fatigue, muscle or joint pain. These side effects are generally mild and last between 2 to 14 days after starting Truvada. Some people experience ongoing GI symptoms. Clinicians should discuss these side effects with patients and possible ways of mitigating them.
2. **Kidney**: Changes in kidney function in HIV negative patients on Truvada have been reported, usually in the first 12 weeks of use. This trend is reversible when Truvada is stopped, and in many cases, patients can safely restart Truvada. Patients who have diabetes and/or hypertension may be at increased risk of kidney problems and may need closer monitoring of kidney health by a PCP.
3. **Bone**: Small declines in bone mineral density have been reported in studies, although this has not been associated with an increase in bone fractures. We do not know the long-term effects of Truvada on bone health in HIV negative patients. If patients have a history of a pathological fracture or bone disease, consider closer monitoring of bone health.
4. **BMD loss in youth**: There are new data that show a small reduction in BMD in young men ages 18-22 on PrEP. Because bones may still be developing in early 20s, the risks/benefits of PrEP should be discussed carefully with patients in this age group and weighed alongside the risk of getting HIV. Unfortunately, there is not at this time any clearer guidance.
5. **Liver**: None, no special liver monitoring is required unless the patient has a history of liver disease or chronic HBV or current HCV infection.

## 7. **Creatinine/Creatinine clearance (CrCl), urinalysis, hepatitis B, hepatitis C**

### **Creatinine and CrCl Monitoring**

For PrEP, desired CrCl is  $\geq 60$ . Calculate creatinine clearance for every creatinine result using this online calculator: <http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault>.

For all abnormal creatinine/CrCl results, document other potential causes of creatinine elevation. Factors that can cause creatinine elevation include large muscle mass, high protein intake (meat, protein supplements), body building supplements (creatine, testosterone), dehydration, and other chronic medical conditions. Medications that can cause abnormal creatinine include trimethoprim, cimetidine (Tagamet), acyclovir/valacyclovir, NSAIDs.

**Intake:PrEP initiation is delayed until creatinine result is received due to medical concern:**

1. CrCl  $\geq 60$  → ok to initiate PrEP.
2. CrCl  $< 60$  →

- Do not initiate PrEP until further medical evaluation can be done. Creatinine testing repeated as soon as possible, preferably within 7 days.
- Perform clean catch UA to look for elevated protein or glucose
- Document other potential causes of creatinine elevation
- MD consult

If repeat CrCl  $\geq 60$ , ok to start PrEP. Repeat creatinine at 1 mo f/u visit.

If repeat CrCl  $< 60$ , do not prescribe PrEP. Arrange for f/u with PCP.

#### Follow-up Visits:

Creatinine check at 3-month follow-up; if stable continue to test every 3-6 months. A rise in creatinine is not a reason to withhold PrEP if CrCl is  $\geq 60$ . If patient has chronic medical conditions such as hypertension or diabetes, consider more frequent creatinine monitoring, but at least every three months.

1. CrCl  $< 60$  → contact patient and consider asking them to stop Truvada, depending on recent HIV risk
  - Repeat creatinine as soon as possible, preferably within 7 days.
  - Perform clean catch UA to look for elevated protein or glucose
  - Document other potential causes of creatinine elevation
  - MD consult

If repeat CrCl  $< 60$ , repeat creatinine in 1-4 weeks, MD consult

If repeat CrCl  $\geq 60$ , ok to restart PrEP and repeat creatinine in 1 month

2. Worsening CrCl, such as CrCl  $\geq 60$  but declining by 20% or more and CrCl  $> 100$  →
  - Continue Truvada and repeat creatinine in up to 4 weeks
  - Perform clean catch UA to look for elevated protein or glucose
  - Document other potential causes of creatinine elevation
  - MD consult/consider stopping PrEP if kidney function continues to worsen

Patient's weight is done at every PrEP visit.

#### Urinalysis

- Urinalyses are not done routinely for patients on PrEP. Perform a urine dip in clinic for creatinine clearance  $< 60$  or CrCl  $< 100$  if declining by 20% or more.
- If dip positive for protein (1+ or greater), send to ARUP for formal UA (see **Section 8** for specimen testing). If timing does not work for sending urine at this visit, schedule next visit between 11-1pm so that repeat UA may be done and sent to ARUP if proteinuria persists.
- If formal UA is positive for proteinuria, repeat formal UA at next quarterly visit to determine if it is persistent.
- MD consult if proteinuria persists

### **Hepatitis B Surface Antigen screening**

- HBsAg screening at intake visit. If positive, check hepatitis B viral load (VL) (ARUP: Hep B virus DNA quant RT-PCR). If VL positive indicating acute or chronic hepatitis B, patient should receive PrEP from PCP.
- Recent hepatitis B vaccination? Delay HBsAg testing until 4 weeks after vaccination to avoid false positive result. PrEP should not be delayed.
- If HBsAg positive and VL negative, consult with MD (patient may need further testing).

### **Hepatitis C Antibody screening**

- All PrEP patients should be screened at intake and yearly while on PrEP.
- Test patients using City Clinic rapid hepatitis C antibody test/protocol. If positive ab result, blood specimen is automatically sent to lab for VL testing. If the HCV viral load is positive and the patient does not have primary care, send specimen for liver function testing (LFTs) to ARUP.
- PrEP can be initiated or continued for patients with existing or new diagnosis of hepatitis C. Consult with MD if questions.

## **8. Lab: specimens and results**

1. All PrEP-specific specimens (creatinine, HBsAg, etc.) will be sent to ARUP for processing. A separate ARUP requisition should be completed for each type of specimen, e.g., 1 specimen for creatinine; 1 specimen for all hepatitis testing. Specimens should be centrifuged and refrigerated at the end of the day if they are not sent to ARUP on the same day. Specimens are viable for 7 days if refrigerated (although they should be sent as soon as possible).
2. Medical Couriers Dispatch picks up specimens Monday, Wednesday, Friday between 12-1pm. To arrange for additional pick-ups call by 1:00 p.m. on the day the pick-up is needed.
3. Results are found online at ARUP Connect: <https://www.aruplab.com/ii/login.jsp>. All PrEP staff have individual log-in capabilities. (The PrEP Coordinator can create new log-ins.) ARUP Connect sends automatic emails when lab results are ready (usually within 48 hours of shipping).
4. PrEP labs are printed from ARUP website twice a week. PrEP staff will enter labs into ISCHTR. The PrEP clinicians responsible for lab results review and sign off on all lab results. All creatinine labs are entered into ISCHTR by PrEP staff.
5. Monthly invoices can be accessed at ARUP Connect and paid online with a credit card. The PrEP coordinator will transmit these invoices to Operations for payment.

## **9. Contact Information**

The PrEP Navigation Services contact number. This may be used by patients to contact PrEP staff or by anyone wanting information about accessing PrEP.

## **10. Discontinuing PrEP**

1. If a patient chooses to discontinue PrEP, they should receive counseling on HIV risk reduction strategies **including PEP**, as well as education on safely restarting PrEP. If the

patient has not yet stopped PrEP, discuss continuing PrEP for 28 days after a high risk exposure if that exposure occurred within the past 7 days.

2. If a patient discontinues PrEP due to seroconversion, they should receive linkage to care with SFCC LINCS team. Patients who have Medi-Cal or who are uninsured and eligible for either Medi-Cal or Ryan White should be offered immediate ART either through SFCC or through the RAPID program at SFGH.

## **11. Charting**

All appointments and interactions with a patient who is registered for a City Clinic visit should be charted in CCEMR.

### **Charting for a PrEP SFCC visit**

1. The following should be documented in CCEMR (for a full list of required charting elements, see *Appendix G*:

- PrEP as reason for visit
- PrEP as diagnosis
- Prescription written
- Follow-up desired (“PrEP follow-up visit” 1, 2, or 3 months)
- Weight
- Clinician progress note
- Counseling note (as needed)
- PrEP tab
  - a. Intake or follow-up?
  - b. Source of Truvada
  - c. Adherence (only for follow-up visits, not intakes)
- **New Enrollment into PrEP program**
  - a. The PrEP Navigator should enroll the participant and chart in CCEMR “PrEP” tab according to the following definitions:
    - i. 0 – Started Process of Getting PrEP**
      1. Patient intends to enroll in the SFCC PrEP program and has taken initial steps toward enrollment, but has not yet been prescribed PrEP. Initial steps toward enrollment include:
        - a. Started Gilead application but didn't submit yet; submitted Gilead Application, awaiting approval; Gilead application approved, waiting for patient to return for intake procedures.
        - b. Started intake procedures, defined as PrEP initiation labs (HIV test, HBsAg, HCV, creatinine clearance) drawn and waiting for results; or postponed writing prescription until clinical concerns resolved.
      2. Record Data in CCEMR:
        - a. Click “NEW” in PrEP tab. Do not enter an enrollment date. The date the client “started the process” is recorded as an automatic date in the background in ISCHTR.
    - ii. 1 – Getting PrEP at SFCC**

1. Patient has a prescription for PrEP (1 or 3 months) written in the past 6 months, and has not told the PrEP team or clinician that they intend to transfer PrEP care.
  2. Record Data in CCEMR:
    - a. Click “NEW” in PrEP tab.
    - b. Change Status to “GETTING PREP AT SFCC”
    - c. Enter enrollment date as date of visit prescription for PrEP written.
- **Completing Enrollments:**
    - a. When a client is no longer taking PrEP, the PrEP navigator should record one of the following statuses:
      - i. 2 – Getting PrEP Elsewhere
        1. Patient has informed PrEP team that they are now getting their PrEP from a primary care provider or another clinic.
        2. Complete date is when PrEP Navigator confirms transfer of care. If not available, record complete date as date of last prescription. If patient mentions at their PrEP visit that they plan to transfer care before the next quarterly visit, instruct the patient to contact us to let us know when they got a prescription from the new provider so that we discharge at that time. Also remind the patient that if they forget to notify us, they will remain enrolled in our program (as “Getting PrEP at SFCC”) and will receive a reminder text for the next quarterly visit, and to please respond at that time to confirm they successfully transferred care.
      - ii. 3 – Stopping PrEP
        1. Patient has informed PrEP team that they plan to stop taking PrEP or have already stopped taking PrEP.
        2. Complete as of date of last pill as reported by patient. **If not available, record complete date as date of last prescription, unless the date of last prescription is the same as the enrollment date. If the two dates are the same, record complete date as 1 month after the enrollment date.** Also, write a progress note explaining patient’s reasons for stopping PrEP.
      - iii. 4 – Lost to Follow Up
        1. Patient has not had a prescription written for PrEP at City Clinic in 6 or more months AND does not have evidence of telling City Clinic staff that they plan to transfer care (2 – Getting PrEP Elsewhere), stop taking PrEP (3 – Stopping PrEP), or move (5 – Moved Away)
        2. Complete date recorded as date of last prescription.
      - iv. 5 – Moved Away
        1. Patient has informed PrEP team that they are moving and will no longer access care at City Clinic.
        2. Complete as of date of last prescription.
  - **New vs. Existing in Enrollment:**
    - a. If the patient returns after being away from City Clinic less than 6 months, there should NOT be a new enrollment for the patient, except in the following circumstances:
      - i. The prior enrollment had already been closed OR

- ii. The patient reports that they never filled prescription or never started PrEP in the first place. If this occurs, the initial enrollment should be closed. Status for that enrollment should be changed to “stopping PrEP” with discharge date as the same date as the enrollment date. Then, a new enrollment should be created. However, if the time that elapsed between the original enrollment date and when the patient actually started taking PrEP is less than 1 month, do not enter a new enrollment.
  - b. If the patient returns after being away from City Clinic 6 months or more, discharge previous enrollment with a change of status for the previous enrollment:
    - i. Status changed to 2 – Getting PrEP Elsewhere, 3 – Stopping PrEP, 4 – Lost to Follow Up, or 5 – Moved Away based on the information provided by the patient.
    - ii. Complete Date is the date of last pill taken reported by the patient (from December 2017 onward, previously date of last prescription.)
    - iii. Create a new enrollment following the guidelines above for new enrollment.
- **HIV Seroconversion: Completing Enrollments:**
  - a. If a patient in SFCC PrEP program (“Getting PrEP at SFCC”) is diagnosed in clinic or elsewhere, the medical director will review the case for possible PrEP failure, including adherence assessment.
  - b. Close the enrollment as “Stopping PrEP”
  - c. Complete as of Date of last PrEP pill taken.
- 2. Using Virtual Chart “Notes” tab, “Progress Note for today,” PrEP clinician should write a note for the patient following the SOAP note format. PrEP progress note template is located on all desktop computers in clinician charting and exam rooms. The progress note should contain the following information: indication for PrEP, timing of most recent HIV exposure, assessment of recent STI/ARI symptoms; history of kidney, liver, bone disease/bone fractures, or other serious medical conditions (at PrEP intake visit and PRN); Truvada side effects (at PrEP follow up visits); weight and blood pressure (at PrEP intake and PRN); adherence/risk reduction counseling and concerns; insurance status/plan.

If the patient is seen by a counselor, the counselor may also add a progress note, as needed. Counselor should document extensive counseling, case management, and/or referrals.

### **Charting for a PrEP consult**

1. Using Counseling tab, “Counseling notes,” PrEP staff should write a brief note about the consultation. This can include education/counseling given, patient’s concerns/questions, insurance status, and/or plan to access PrEP.
2. Under “F/U & Referrals” tab, “Referrals,” the “PrEP consult Completed” box should be checked.

## **12. Counseling**

Every appointment should include a counseling check-in with the patient and a psychosocial needs assessment. At the first consultation and/or the intake appointment, the clinician or counselor should conduct HIV/STI risk assessment and counseling, as needed. At the initiation visit, medication adherence counseling should be conducted. At follow-up visits, the clinician or

counselor should check in with the patient regarding HIV/STI risk and medication adherence and provide counseling as needed or desired. See *Appendix D* for suggested counseling prompts and topics.

### **13. PrEP procedures for travelers**

In certain instances, SFCC can provide PrEP to patients who are not able to come to the clinic for all of their visits, either because of relocation or lengthy travel. Here are the guidelines for travelers.

1. All patients seeking PrEP at SFCC must have in-person initiation appointment following procedures set out above.
2. If a patient is not able to come to SFCC for follow-up visits, the following procedures are followed:

#### 2-week phone check-in

#### 3-month follow-up

- Be available for phone check-in
  - Send creatinine, negative HIV result, and STI testing results
  - We will call or fax a prescription for 30 days + 2 refills or 90 days
3. SFCC cannot ship medication to patients.
  4. SFCC will follow travelling patients on PrEP for a maximum of 6 months. Exceptions will be made at the discretion of the PrEP coordinator.
  5. For patients seeking a vacation override with Gilead PAP, counsel them as follows:
    - Vacation override can only be used 1x/lifetime with the Gilead PAP.
    - Prescription must be written as #90.
    - Patient should try to fill at the pharmacy, and get a denial. Then patient should contact the SFCC PrEP team to notify them this was done, and the specific pharmacy location where they went.
    - At this time, PrEP team will call Gilead to request the override. The override takes 24-48 hours to take effect, meaning that patients need to request this procedure at least 3 days before leaving town.
    - Gilead will notify SFCC PrEP team when override has been entered. Ultimately, it is the patient's responsibility to check with pharmacy to make sure it went through.

### **14. Retention**

PrEP staff carry out numerous retention procedures for patients enrolled in the PrEP program. These include 2-week contact after initiation, reminder contact for follow-up appointments, reminder contact for missed appointments, follow-up contact to patients who report that they are stopping PrEP, getting PrEP elsewhere, or who have changes in insurance status or Gilead PAP eligibility (i.e., PrEP access). In some cases, follow-up contact is also made for patients who are lost to follow-up.

"Contact" is defined as a phone call, a text message, and/or an email. Contact is further defined as one attempt to get in touch with the patient. PrEP staff may in its discretion contact the patient more than once, depending on other circumstances, such as known high-risk for HIV, positive STD results, other psychosocial circumstances, insurance status.

1. Gilead medication assistance program (MAP) applications: incomplete. If a patient starts a Gilead MAP application while in the office but doesn't complete it, the application is stored in the PrEP file cabinet. The progress note for the visit at which the application was started should specify what is missing from the application and the plan for completing it. PrEP navigators should make at least \_\_ attempts over 2 weeks to remind the patient to complete the application. If after \_\_ attempts the patient does not respond, the incomplete application should be scanned into CCEMR and a progress note added to CCEMR recording the contact attempts and outcome.
2. Gilead medication assistance program (MAP) applications: approved. When we receive an approval letter for a patient's enrollment in the Gilead MAP, the patient should be informed. Enrollment pharmacy enrollment information is available from Gilead MAP the day after the approval is given. The PrEP navigator should contact Gilead for that information. If the patient has already completed the initiation process and received a prescription, the PrEP navigator will contact the patient with the Gilead pharmacy enrollment information and instruct them to go to the pharmacy as soon as possible to fill the prescription. If the patient has not completed the initiation process, the PrEP navigator will contact the patient and inform them to return to clinic as soon as possible for PrEP initiation. In either of the above cases, the PrEP navigator will make 1 attempt monthly to notify the patient that they are eligible for Gilead's PrEP assistance, until the eligibility period expires. The approval letter should be attached to the Gilead MAP application and kept in the PrEP file cabinet. If by the time the eligibility period expires, the patient does not return to clinic, the approval letter and application should be scanned into CCEMR and a progress note should be added recording the contact attempts and outcome.
3. 2 weeks post-initiation. PrEP staff will contact patients two weeks after initiating PrEP at City Clinic to confirm that the patient filled the prescription and started taking PrEP. PrEP staff will assess side effects and adherence and address problems as needed and according to the other provisions of this protocol. When indicated, a patient may be asked to return to the clinic to see a clinician, or a clinician may contact a patient to obtain further information about symptoms, side effects, or other medical concerns.
4. 2 week reminder texts pre-visit. PrEP staff will contact the patient 14 days before our records show the last prescription will run out to remind the patient to return to the clinic for a follow-up visit.
5. 2 weeks overdue. PrEP staff will contact the patient 10-14 days after our records show the patient should have returned to the clinic but failed to do so (missed visit).
6. Patient to access PrEP outside of City Clinic. When a patient reports to PrEP staff they will start getting PrEP prescriptions and follow-up with another provider, PrEP staff will contact the patient 1-3 months after that announcement (depending on the length of prescription given at the last City Clinic visit) to confirm that the patient was able to see the new provider and get a new prescription.

7. Stopping PrEP. When a patient reports they want to stop PrEP, the PrEP staff should follow this protocol for advising when it is safe for the patient to stop (i.e., 28 days after the last exposure). PrEP staff will contact the patient 1-3 months after the patient has stopped to check in with the patient to see if they continue to want to be off PrEP.
8. Change in insurance status/PrEP access. When a patient reports a change in insurance status or when an uninsured patient's eligibility for the Gilead PAP is about to expire, PrEP staff will contact the patient to help the patient take necessary measures to have continuous access to PrEP. This includes supporting the patient in getting information from their employer and/or insurance carrier regarding status; reminding the patient to apply for Medi-Cal (if eligible); and helping the patient complete a new application for the Gilead PrEP PAP.
9. Lost to follow-up. In cases when a patient is lost to follow-up, PrEP staff may in their discretion continue to contact patient to ascertain HIV risk, PrEP status, other circumstances.
10. For detailed procedures of how to run retention lists and contact patients, see Appendix H.

## **15. Providing PrEP to participants of Bridge HIV vaccine studies**

Participants of the HIV vaccine or broadly neutralizing monoclonal antibody studies at Bridge HIV have the option to receive PrEP from Gilead for the duration of their participation. SFCC can see these participants to authorize their Truvada prescriptions and to provide PrEP follow-up. The applicable procedures outlined above for intake, first dispensation, and follow-up should be followed. If participants have been unblinded and are known to have received placebo, they can have HIV testing at SFCC per the PrEP protocol. However, if they are in the blinded phase of the study, or received the vaccine product, they cannot take a rapid HIV antibody test at SFCC. For these participants, see *Appendix F* for guidelines on HIV testing. All study participants receiving PrEP from SFCC should sign a medical records release so that Bridge can provide HIV results to SFCC. The SFCC PrEP clinician/PrEP staff will arrange to have all bottles of Truvada shipped to SFCC for dispensing. See *Appendix E* for prescription guidelines.

## **16. PrEP Resources**

- [sfcityclinic.org/services/prep.asp](http://sfcityclinic.org/services/prep.asp)
- [projectinform.org/prepresources/](http://projectinform.org/prepresources/)
- [prepfacts.org/](http://prepfacts.org/)
- [myprepexperience.blogspot.com/](http://myprepexperience.blogspot.com/)
- [cdc.gov/hiv/basics/prep.html](http://cdc.gov/hiv/basics/prep.html)
- [Clinician Consultation Center PrEPline: \(855\) HIV PrEP \(855-448-7737\)  
nccc.ucsf.edu/clinical-resources/pep-resources/prep/](http://nccc.ucsf.edu/clinical-resources/pep-resources/prep/)
- [Gilead: truvadapreprems.com \(for clinicians\)](http://Gilead:truvadapreprems.com)