

MAGNET CLINICAL PROTOCOLS	Page 1 of
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Policy Section: Patient Care	
Pre Exposure Prophylaxis Health Program	

Back ground: The advent of combined behavioral and biomedical interventions for prevention of HIV transmission, and the Affordable Care Act, creates an opportunity to reach healthy populations to promote safer and more satisfying sexual practices. More than 50,000 new HIV infections occur in the United States every year, and this rate has not changed in 20 years. In San Francisco, there are more than 400 new HIV diagnoses every year, or more than one per day, with no change over the period 2010 to 2013. Pre-exposure prophylaxis (or PrEP) using oral FTC/TDF was approved by the FDA in 2012, the CDC has issued guidance for use, and insurance providers are paying for this service. Early indicators suggest that demand for PrEP in San Francisco among MSM is growing since clearer information about safety and efficacy became available last year. As a medical and cultural leader in health practices, SFAF is poised to host the first sexual health clinic that will offer PrEP. This advance could be leveraged to develop an ever-expanding set of services aimed to prevent disease and foster wellness. (UCSF SOP)

Client Eligibility for Services: All clients who live in the San Francisco Bay Area will be eligible to be screened for PrEP. The client must be able to return to Magnet to receive follow up care.

Healthy Clients: Due to the limited ability to provide comprehensive primary care at Magnet, Clients must be in good health to be enrolled in the PrEP Program. Those with certain health conditions, as determined by the NP/MD, may be referred to a primary care provider if the care and follow up needed is beyond the service capacity of Magnet.

Scope of Care: Clients presenting to the PrEP Health Program are not required to have a primary care provider to access PrEP. Magnet will provide care and monitoring related to PrEP but will not treat unrelated conditions. The benefits coordinator will assist the clients in enrolling in insurance programs and encourage the client to establish care with a primary care provider. Magnet will provide prescriptions for PrEP and medications used to manage side effects related to PrEP use (e.g. Phenergan for Nausea).

Screening and Enrollment into the PrEP Health Program:

Screening and Enrollment visits into the PrEP Health Program may occur simultaneously or at separate visits depending on the availability of staff and the client’s schedule. All parts of the screening visit and enrollment must be completed prior to initiation of PrEP. Screening labs should be repeated if the enrollment occurs more than 30 days after the initial screen.

Screening Process: Clients may enter the screening process in three ways.

1. During a routine HIV/STI screening visit, the counselor and the client may identify PrEP as a potential HIV risk reduction strategy. These clients may be scheduled for a PrEP screening visit for another day or may be seen the same day if there is an available appointment.
2. A client may have already identified PrEP as a potential HIV risk reduction strategy. These clients may be scheduled for a PrEP visit.
3. A client who enters the nPEP program will be offered PrEP after completing the course of nPEP.

Appointments will be made under the same guidelines as other appointments by walk in or online for established clients.

PrEP Enrollment: The PrEP enrollment can be completed in two different paths depending on the availability of staff. One path will be RN/NP/MD based and the other path will be NP/MD.

The steps needed in a PrEP Health Program intake involve:

1. Registration paperwork
2. Routine HIV/STI visit
3. PrEP Eligibility
4. Obtaining health history
5. Reviewing current medications
6. Performing a physical exam
7. Reviewing lab results
8. Clinician Assessment for PrEP or PEP
9. Provide PrEP Counseling
10. Discussing adherence strategies
11. Providing the prescription
12. Referring to the benefits counselor
13. Notification of client's PCP

NP/MD path: The NP/MD path involves the NP/MD completing the baseline PrEP Eligibility form, collecting the health history, reviewing the medications, performing a physical exam, reviewing the point of care tests, determining eligibility for PrEP or PEP, discussing adherence, writing a prescription, referring to the benefits coordinator, and notification of the client's PCP.

RN/NP/MD path: The RN/NP/MD path involves the RN completing the initial baseline PrEP screening form, collecting the health history, reviewing the medications, discussing adherence, and referring the benefits coordinator. Once the RN has completed these tasks, the NP/MD will review the collected information, perform a physical exam, determine eligibility for PrEP or PEP, and write a prescription.

License required for each step

	HIV Counselor	RN	NP/MD	Benefits Counselor
<i>HIV/STI Visit</i>	X			X
<i>PrEP Eligibility</i>		X	X	
<i>Health History</i>		X*	X	
<i>Medications</i>		X*	X	
<i>Physical Exam</i>			X	
<i>Lab Tests</i>		X	X	
<i>PrEP Assessment</i>		X*	X	
<i>PrEP Counseling</i>		X	X	
<i>Adherence</i>		X	X	
<i>Prescription</i>			X	
<i>Benefits Counseling</i>		X	X	X
<i>PCP Notification</i>		X	X	X

*These steps need to be verified by an NP/MD

Registration Paperwork: The client will complete the routine registration information, Day of Visit Risk Assessment, HIV Testing Consent, and the PrEP Consent.

HIV/STI Testing: The initial screens and follow up visits will be incorporated into the routine HIV/STI testing flow. The clients will initially meet with an HIV testing counselor for their routine screening then meet with the RN/NP/MD for the completion of their PrEP visit

PrEP Eligibility: A PrEP eligibility tool adapted from CDC guidelines will be used to determine the appropriateness of PrEP Health Program provided by Magnet.

Eligibility Criteria

- 1) Age 12 and Over
- 2) Lives in the San Francisco Bay Area
- 3) HIV Negative
- 4) At risk for HIV (should meet one criteria)
 - a. At least one episode of condomless anal/vaginal sex in last year
 - b. HIV+ sexual partner
 - c. At least one episode of sharing a needle in the last year

Exclusion Criteria

- 1) Renal disease*
- 2) Liver disease including chronic hepatitis B
- 3) Osteoporosis*
- 4) Pregnancy
- 5) Acute viral syndrome
- 6) High risk HIV exposure less than 72 hours from enrollment
- 7) Uncontrolled Diabetes
- 8) Abnormal screening labs not explain by comorbid condition
- 9) Any other conditions that are deemed contraindicated for PrEP by the NP/MD

*Clients with existing renal insufficiency or bone loss may be offered emtricitabine/tenofovir alafenamide for PrEP per Descovy for PrEP protocol.

In the absence of contraindications or special circumstances, PrEP should be provided upon request, even if risk factors are not reported, given that some risk factors are under-reported. Provider predictions of future adherence are not reliable, and PrEP should not be withheld from someone because of concerns about future adherence.

Health History: A complete health history will be documented in the client record

Medications: All medications currently prescribed to the client and over the counter (including supplements) will be recorded in the client record.

Physical Exam: An initial full physical exam will be completed

Lab Tests: A comprehensive medical panel, Hepatitis B AG, Hepatitis C AB, and rapid HIV/RNA will be collected the initial evaluation. PrEP may be initiated with the Hepatitis AG and RNA pending if there is a low suspicion for HBV or HIV infection. If nPEP is not indicated, the RNA may be pending. If the client has been vaccinated or is in the process of vaccinating for Hep B or has a low risk of having an undiagnosed chronic HBV, the hepatitis B AG may be pending. Renal and liver function tests should be within normal limits unless explained by a known health condition that is not contraindicated. Hepatitis C antibody is ordered for all clients who do not have a history of Hepatitis C.

eGFR in Transgender Men and Women: Transgender men on testosterone are more likely to have increased muscle mass and Transgender women do not lose muscle mass. As a result, the male reference ranges for eGFR should be used for both Transgender Men and Women.

PrEP Assessment: The final assessment of the appropriateness for the PrEP Health Program will be made by an NP/MD. The determination will be based on:

1. PrEP Eligibility
2. Health History
3. Medications
4. Laboratory results

Clients who are determined ineligible due to medical conditions may be referred to a Primary Care Provider for PrEP management.

Special Considerations:

- 1) Injection drug users. Oral TDF PrEP was effective for prevention of HIV acquisition among IDUs in Thailand, having limited access to clean needles. Oral FTC/TDF has not been specifically evaluated, but is expected to be at least as effective as oral TDF PrEP. Whether oral FTC/TDF PrEP provides additional benefit to ready access to clean needles is not known. PrEP may be provided to IDUs along with a renewable supply of clean needles.

- 2) Active HBV infection (HBsAg+). Daily oral FTC/TDF is active against HBV and is a recommended treatment for HBV infection. Discontinuation of such therapy may involve a high risk of hepatitis flare in the setting of HBV cirrhosis; such flares can be severe leading to fulminant liver failure. The risk of flare is lower if cirrhosis is not present at baseline. Experience with the use of oral TDF-containing PrEP in persons with HBV infection is limited. Use of PrEP in the setting of HBV requires additional counseling regarding the risks of stopping PrEP, and regular monitoring of liver enzymes and HBV viral load and HBV drug resistance testing if viral load becomes detectable. These services are not provided at Magnet. Clients requiring PrEP and treatment of HBV will be referred to a primary care provider.
- 3) Abnormal serum creatinine. PrEP has not been evaluated in people with abnormal baseline renal function. Most creatinine elevations are self-limited, transient, and due to the common causes listed in this protocol. If a client has an abnormal creatinine/eGFR at evaluation, the creatinine/eGFR should be repeated on a second Piccolo machine. If that value is normal, it may be accepted as valid. If the repeated value is abnormal, a creatinine and cystatin c should be sent to ARUP. If the cystatin c is normal and the creatinine is normal or abnormal in the setting deemed by the NP/MD to be due to common causes, the client may start emtricitabine/tenofovir disoproxil fumarate disoproxil fumarate. The NP/MD may initiate emtricitabine/tenofovir disoproxil fumarate with the cystatin c and confirmatory creatinine pending if the creatinine elevation is assumed to be from increased muscle mass.
- 4) Acute Viral Syndrome. Starting a 2 drug PrEP regimen during acute HIV infection is associated with a 50 to 100% risk of acquiring FTC resistance mutations in the viral population and is to be avoided. Acute HIV infection typically induces an acute viral syndrome with non-specific findings. More than 70% of people with acute infection will have one or more of the following findings: sore throat, fever, nasal congestion, rash, myalgias, arthralgias, thrush. The findings are non-specific for HIV. Individuals with an acute viral syndrome should not start a 2 drug PrEP regimen. If there has been a recent exposure to fluids that are possibly HIV infected in the past 72 hours, they follow the nPEP protocol. If there has been no exposure in the past 72 hours, the provider may a presumptive HIV treatment (off label) or deferring PrEP until the acute viral symptoms resolve and the HIV test is repeated and negative.

Post Exposure Prophylaxis: Clients reporting recent high-risk exposure to HIV in the last 72 hours should follow the nPEP protocol. Clients will be given priority enrollment into the PrEP Health Program once completing nPEP to ensure continuity of treatment.

Presumptive Acute HIV Treatment: Clients reporting a high-risk exposure to HIV 14 to 3 days before may initiate a 3-drug regimen including emtricitabine and tenofovir alafenamide (Descovy) 200/10mg with dolutegravir (Tivicay) 50mg or bicitgravir/emtricitabine/tenofovir alafenamide 50/200/25mg to presumptively treat HIV. Clients who have a recent high-risk exposure may have future exposures and require immediate PrEP initiation. If the client has been infected with HIV from the exposure, the client will benefit from early treatment. The client follow up is to be scheduled as a PrEP enrollment to allows for 2 monthly follow up visits to rule

out a baseline HIV infection. An individual HIV RNA should be ordered at baseline. Consult with MD for proper follow up.

PrEP Counseling: Client centered PrEP counseling will be provided at enrollment and at all follow up visits. Providers will discuss the risks and benefits of PrEP and additional prevention strategies in the context of each client's sexual history. The alternative strategies to be considered include consistent condom use, strategic positioning, seroadaptation and serosorting, and negotiated safety. The discussion of the benefits of PrEP will include that PrEP can reduce HIV rates by 96% or more if taken daily. However, daily use is challenging and was accomplished by only about 20% of study participants overall. Less frequent use of PrEP provided lower levels of protection, or no protection at all. 90% of PrEP users do not experience side effects. About 1 in 10 PrEP users had nausea or abdominal cramping that resolves after the first few weeks of continued use. Approximately 1 in 200 PrEP users had elevations in serum creatinine confirmed on repeat testing on a new specimen. Such elevations were reversible after stopping PrEP and did not recur after restarting. This risk is managed by requiring serum creatinine testing every 3 months. PrEP users also had an average 1% loss in bone mineral density, which was too small to result in any bone fractures, and there were trends toward resolution of bone changes after stopping PrEP. Written materials describing different harm reduction strategies and PrEP will be made available to everyone. The limitations of PrEP will also be discussed, including that benefits require daily adherence, and that PrEP does not prevent STI's other than HIV (including syphilis, herpes, GC, HBV, HPV, and HCV) and does not prevent pregnancy. If the client has female partners, or is a woman of reproductive age, the provider should ask about reproduction goals and plans, and provide contraception counseling and prescriptions as indicated. Condoms will be encourage to be used with emtricitabine/tenofovir disoproxil fumarate. Condoms may not be feasible for all clients. Each client will make their own personal choices on how to protect himself or herself. The use of condoms is not required to be on emtricitabine/tenofovir disoproxil fumarate. PrEP counseling will include questions including

- What do you know about PrEP?
- What do you want PrEP to do for you?
- What have you heard about PrEP and condoms?

Daily PrEP vs PrEP 211: As part of PrEP Counseling, the client will be offered the options of daily PrEP or PrEP 211. Clients electing PrEP 211 should follow the PrEP 211 dosing protocol.

Stigma Counseling: There have been anecdotal reports of stigma related to the use of PrEP, which had resulted in loss of employment, housing, friends, and family. The use of PrEP is seen as controversial by some organizations. In order to prevent any negative social consequences from PrEP use, PrEP counseling should address how the client's use of PrEP would impact their housing, employment, friends, and family. If there is an identified problem, the RN/NP/MD should work out a feasible plan with the client, which may involve the use of pill boxes, family counseling or other measures to discretely incorporate the use of PrEP in their lives.

Adherence Counseling: A brief interactive client centered counseling session will be conducted to highlight possible short term side effects of oral FTC/TDF, including nausea, abdominal cramping, and headache. The importance of adherence for obtaining the benefits of PrEP will be

discussed. One adherence strategy will be identified and recorded. Possible strategies to suggest include linking the dose with a daily activity that occurs every day, even when traveling or staying out late, such as brushing teeth or hair, a morning shower, or waking up. Oral FTC/TDF can be taken any time during the day, at different times on different days, and with or without food. In general, people using daily medications in the morning tend to be more successful than dosing occurring later in the day. If people forget a dose, they should take the dose when they remember if the same day. If they do not recall whether they have taken a dose on a given day, they should take a dose.

- The protection you get from PrEP is directly related to how good you are at taking pills. It can be challenging. Getting into a routine can help you remember to take your pills. What routine do you get into every day that would help you remember to take your pills?

Prescription: All clients who are deemed eligible by the NP/MD and have completing the adherence and PrEP counseling will receive a prescription for emtricitabine/tenofovir disoproxil fumarate. Enough medications to last for 30 days after the next follow up visit will be provided. The prescription should be written for Truvada (emtricitabine/tenofovir disoproxil fumarate) Take 1 pill by mouth daily for PrEP. #30. Refills 1.

Benefits Counselor: The role of the benefits counselor is to facilitate the enrollment into health insurance programs and patient assistance programs in order to access PrEP at a reasonable costs. Initially, patient assistance programs may be used in order to have faster access to PrEP. Over time this may not always be sustainable for the client. The goal should be to enroll someone in an affordable health insurance program that covers PrEP at an affordable cost.

Notification of client's PCP: Once a client has been enrolled into the PrEP Health Program, a standard letter outlining the client's enrollment into Magnet's PrEP Health Program will be sent to the client's primary care provider if there is one. Consent must be obtained to notify the client's PCP. If a client does not have a PCP or does not want the PCP notified, a generic letter will be provided to the client for future use.

Phone Check In: On day 3, a phone call will be made to the client to check in about obtaining the medication, side effects, and answer any additional questions.

Follow-up visits: Those electing PrEP will be offered follow-up visits at month 1 and every 3 months thereafter until the client withdraws from the program. All follow up visits will include a creatinine/bun/egfr, Urine Pregnancy (if applicable) rapid HIV and RNA testing, adherence counseling, risk reduction counseling, symptom assessment, health history updates, medication updates and prescription refill. Benefits counseling will be provided as needed. Hepatitis C will be offered based on the Hepatitis C protocol.

HIV Testing: Clients reporting sexual contact without a condom and while off PrEP which is defined:

1. Missing 4 doses in the 7 days for anal sex around the sexual encounter
2. Missing 2 doses in the last 7 days for vaginal or front hole sex around the sexual encounter
3. Not using PrEP 211 as instructed or with each sexual encounter

Should have a Rapid HIV Stat-Pak preformed at their visit.

This may be elicited by asking “Have you had sex off PrEP?”

Clients who report full adherence and deny any sexual contact off PrEP or without a condom will have a pooled HIV RNA only at their visits and do not need a Rapid HIV test due to low risk of HIV.

All clients may elect to have a Rapid HIV AB Stat-Pak upon request.

To cover the rare chance of an HIV-2 infection that is not picked up by a Pooled HIV-1 RNA, all clients will receive an annual HIV 4th Gen test.

Adherence Measure: Clients will be asked the following questions to measure adherence. Any reported missed doses require an adherence assessment.

Thinking of the last time you had anal or vaginal/front hole sex, did you take Truvada for PrEP between 2 and 24 hours BEFORE sex?

- Yes-I took 1 pill on that day
- Yes-I took 2 pills at one time on that day
- No
- Not sure/Do not remember

Thinking of this last time you had anal or vaginal/front hole sex, did you take another pill of Truvada for PrEP in the 24 hours (1 day) AFTER sex?

- Yes
- No
- Not yet I had sex less than 24 hours ago
- Not sure/Do not remember

Thinking of this last time you had anal or vaginal/front hole sex, did you take another pill of Truvada for PrEP 48 hours (2 Days) AFTER sex?

- Yes
- No
- Not yet I had sex less than 48 hours ago
- Not sure/Do not remember

Thinking of this last time you had anal or vaginal/front hole sex, select any additional ways you protected yourself.

- Used a condom
- Partner told me they had an undetectable HIV Viral Load - U=U
- Partner told me they were on PrEP
- I only topped
- Other
- None of the above applies

Prescriptions at follow up visits: Prescriptions will be provided with enough medication to last until the 30 days AFTER the next visit. Prescriptions should not be filled if the client does not attend the follow up visits unless the client is traveling or has other special circumstances that warrant a refill without lab work. Prescriptions may be written by the provider or under any provider licensed in clinic with furnishing/prescription privileges. Prescriptions may be called in or prescribed under the Medical Director's prescriptive authority as per the Standardized Procedures for Registered Nurses or Nurse Practitioners. Operating under the Standardized Procedure meets the requirement for Patient Eligibility under 602 VHA 1992 for the 340B program. The prescription should be written for Truvada (emtricitabine/tenofovir disoproxil fumarate) Take 1 pill by mouth daily for PrEP. #30. Refills 4. The prescription may be written for 90 days if the insurance allows. Truvada (emtricitabine/tenofovir disoproxil fumarate) Take 1 pill by mouth daily for PrEP. #90. Refills 0.

Follow up Events and RN Management Orders

Elevated creatinine: Creatinine elevation is expected when taking emtricitabine/tenofovir disoproxil fumarate. This may be due to the drug itself, normal variance in the test, or due to changes in a client's medications, diet, or exercise.

A client who meets one of the following two criteria will require further evaluation:

- An eGFR less than 60
- A creatinine measure of 1.65 or above

If a client has an eGFR less than 60, they should be assessed for common causes of creatinine elevation and have a repeat creatinine performed on a different Piccolo machine. If the repeated creatinine and eGFR are within protocol limits, that value may be accepted as valid. The client should be scheduled for routine follow up. If the value remains abnormal, a confirmatory creatinine and cystatin c should be sent to from heparinized plasma. The client may continue to take emtricitabine/tenofovir disoproxil fumarate during this time. The NP/MD will assess the confirmatory cystatin c and creatinine and follow up with the client by phone/email. The client does not need a scheduled visit.

If a client has a creatinine measure of 1.65 or above, the client should be assessed for common causes of creatinine elevation and have a repeat creatinine performed on a different Piccolo machine. If the repeated creatinine and eGFR are within protocol limits, that value may be accepted as valid. The client should be scheduled for routine follow up. If the value remains abnormal, a confirmatory creatinine and cystatin c should be sent to from heparinized plasma. The client should be instructed to stop taking emtricitabine/tenofovir disoproxil fumarate until the client is seen by the NP/MD. A follow up visit to see an NP should be scheduled in a week. If an NP/MD is available at the visit, they may elect to switch the client to emtricitabine/tenofovir alafenamide per protocol.

Further evaluation after an elevated creatinine:

Creatinine elevations may only be assessed by an NP/MD.

If the confirmatory creatinine and cystatin c is within normal limits, the client may continue or restart emtricitabine/tenofovir disoproxil fumarate.

If the cystatin c is normal and the NP has reason to believe the creatinine elevation was due to common causes not related to emtricitabine/tenofovir disoproxil fumarate, the client should be scheduled for routine follow up.

Clients who have elevated creatinine deemed unrelated to emtricitabine/tenofovir disoproxil fumarate and have a normal cystatin-C may continue on emtricitabine/tenofovir disoproxil fumarate. There may be a possibility that a new renal toxicity could emerge and be undetected. Clients who have an elevated creatinine will have the upper limit of creatinine recorded in the chart by the NP and a cystatin C will be performed annually for clients with persistent creatinine elevations. If a client has a follow up creatinine that is elevated but under the limited recorded by the NP, the RN may renew the emtricitabine/tenofovir disoproxil fumarate prescription if there is a cystatin C in the last year. If the creatinine and eGFR is within protocol, the RN will follow the routine follow up protocol. If a client has follow up creatinine that is elevated over the limit recorded or there is no cystatin C in the last year, the RN will follow the elevated creatinine protocol.

If the creatinine and cystatin C are abnormal, renal impairment is considered related to emtricitabine/tenofovir disoproxil fumarate and the medication should be stopped. Serum Creatinine should be repeated at 1 week, 2 weeks, and 4 weeks on the Piccolo until the serum creatinine resolves to within 10% of the baseline creatinine value. The serum creatinine should be lower after 2 weeks. Clients with a serum creatinine that has not decreased after 2 weeks or resolved to 10% of baseline after 4 weeks should be referred to a nephrologist for further evaluation. Once the serum creatinine resolves, Serum creatinine will be rechecked per protocol. Client's with ongoing sexual risk will be assessed and the client may change to emtricitabine/tenofovir alafenamide in those who have on-going risk factors **or an expressed desire to continue.**

Common causes of creatinine elevation

Creatinine can be a poor marker of kidney health and is subject to error based on client behaviors. The following items are known to cause a false elevation in creatinine and should be assessed by the Nurse Practitioner prior to making any changes to a regimen. At all follow up visits with an elevated creatinine, the nurse will document if any of these items apply to the client.

- Normal lab assay variation (cv 12%)
- Increased muscle mass (Clients who have large musculature)
- Exercise
- Dehydration
- Creatinine and muscle supplements
- Increased intake of cooked meats
- Vegetarian diet

- H2 blockers
- Trimethoprim (Bactrim/Septra)
- NSAIDS
- Fenofibrates
- Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs)
- Heroin
- Infections

Other Metabolic labs: Any abnormal metabolic labs should be signed off by an NP/MD. If there are any abnormal labs on a follow up visit conducted by an RN, the labs should be flagged for reviewed by an NP/MD.

Seroconversion or NAT positive procedures: Follow PrEP HIV Seroconversion Protocol

Nausea or vomiting or headaches or heart burn: Gastrointestinal side effects and headaches have been reported with emtricitabine/tenofovir disoproxil fumarate. These side effects are generally self-limiting and resolve within 2 weeks of taking emtricitabine/tenofovir disoproxil fumarate. If a client reports nausea or vomiting the client will be encouraged to take the medication at night and/or with non-spicy food. If the nausea, vomiting, or headaches persists after 4 weeks, PrEP should be reevaluated.

Weight Loss: Weight loss of up to 4% was reported in the iPREX study. This weight loss was recovered after 12 months. It is unclear if emtricitabine/tenofovir disoproxil fumarate is an independent contributor to weight loss or if it is related to nausea from the medication. Clients who report weight loss are to have their weight in KG obtained, be assessed for intentional causes of weight loss such as diet, and exercise or other common causes such as illness. Other new medications other than emtricitabine/tenofovir disoproxil fumarate are assessed. Clients who report 5% or greater unintentional weight loss compared to their baseline weight with no other new medications are to be assessed for recent HIV exposures and if there are no recent exposures, the client should be instructed to stop. The client is counseled around safer sex practices without emtricitabine/tenofovir disoproxil fumarate. The client is to return in 1 month to be reassessed by an NP/MD and rechallenged if deemed appropriate.

Abnormal dreams: Abnormal dreams have been reported with the use of emtricitabine/tenofovir disoproxil fumarate. There are no known proven remedies. The client may try to take the medication in the AM and avoid watching graphic images before bed.

Bone loss: It would be very unusual for the bone loss resulting from emtricitabine/tenofovir disoproxil fumarate to cause bone loss in healthy individuals that result in fracture. If the client reports any suspicious fractures, the medication should be held and further use of emtricitabine/tenofovir disoproxil fumarate must be evaluated by the client's PCP

GC/CT/Syphilis: PrEP does not provide any protection against other STIs. If a client reports multiple STI infections, this is not a reason to discontinue PrEP. All new STI infections will be

handled as if they were not on PrEP. The client will receive appropriate sexual risk reduction counseling and encouraged to notify sexual partners.

Sexual Risk Behavior: PrEP is not known to increase sexual risk behaviors. If a client reports an increase in high risk sex, this will not be a reason to discontinue PrEP. The client will continue to receive appropriate sexual risk reduction counseling.

Pregnancy: Clients of child bearing potential will be given a urine pregnancy test at baseline and at all follow-up visits. If the urine pregnancy test is positive, the client should be referred to an OB/GYN. Emtricitabine/tenofovir disoproxil fumarate is a category B pregnancy medication and should be reported to the ARV Pregnancy Registrar at 1-800-258-4263

Extended stops of emtricitabine/tenofovir disoproxil fumarate: Any break in daily dosing or a delay of emtricitabine/tenofovir initiation of 7 days or more requires a rescreen of HIV if there has been the potential for exposure.

Terminating PrEP: Clients may stop PrEP at any time or Magnet may stop providing PrEP to a client if PrEP becomes contraindicated. If the client opts to stop PrEP, the treatment should be continued for 28 days after the last possible exposure to HIV.

Engagement to PrEP: All clients will be encouraged to actively participate in their care. Magnet will assist clients in adhering to follow up visit, but it is ultimately the responsibility of the client to follow up at the scheduled visits. If a client no shows, they will receive a call on the first day, a call and an email on the second day, and a call, an email, and a letter on the third day. If there is no response, there is no further action needed by Magnet. If the client returns, he/she may reenroll into the PrEP program after proper testing. Refills will not be provided without a follow up visit.

Missed Appointments: It is important for clients to attend follow up appointments to ensure optimal health. Clients who miss appointments should be rescheduled to the next available appointment. If a client runs out of medications and has not attended a follow up appointment, a 1-month prescription of Truvada will be provided and another follow up visit should be scheduled. If the client does not attend that follow up visit, no refills may be given until the client attends the follow up visit.

Provision of initial prescription for clients on a stable PrEP regimen who will run out before an enrollment is available: A 30-day supply of emtricitabine/tenofovir disoproxil fumarate may be provided if a client transferring their care but will run out of medications before their enrollment visit.

Eligibility:

1. Client signed treatment consent in person or online
2. Self-reports being on emtricitabine/tenofovir disoproxil fumarate
3. Meets inclusion and exclusion criteria for PrEP Health Program
4. Negative HIV test within the last 7 days from outside provider or test from Magnet

Exclusion:

1. Kaiser or VA insurance
2. Complex medical history requiring in person evaluation
3. Any symptoms indicative of acute viral syndrome

A telephone note is created, and inclusion and exclusion are documented. A 30-day supply is sent to the client's pharmacy of choice.

The client must attend a PrEP enrollment visit with 30-days.

Off-label use of Descovy (emtricitabine/tenofovir alafenamide fumarate) for PrEP in renal or bone impairment

In an early analysis of the DISCOVER trial released on March 6, 2019, emtricitabine/tenofovir alafenamide fumarate was shown to be non-inferior to emtricitabine/tenofovir disoproxil fumarate for preventing HIV infection. Descovy (emtricitabine/tenofovir alafenamide fumarate) was approved for the treatment of HIV infection in 2016. DISCOVER trial data supporting use of emtricitabine/tenofovir alafenamide fumarate for PrEP was submitted to FDA for review in April 2019, and as of July 2019 is not yet FDA approved, or recommended explicitly by CDC.

Based on currently available evidence, emtricitabine/tenofovir alafenamide fumarate may be offered to clients who have ongoing risk for acquiring HIV who, due to renal insufficiency or osteoporosis, would not otherwise be able to use PrEP as dosed with emtricitabine/tenofovir disoproxil fumarate.

Clients who report baseline bone or kidney related conditions that would exclude use of emtricitabine/tenofovir disoproxil fumarate may be offered emtricitabine/tenofovir alafenamide fumarate as an off-label prevention strategy if glomerular filtration rate (GFR) at baseline is > 30 mL/min. Clients with transient creatinine elevations due to exercise or diet should remain on emtricitabine/tenofovir disoproxil fumarate per protocol.

Patients wishing to use emtricitabine/tenofovir alafenamide fumarate on an off-label basis for PrEP should understand and agree to the following:

“As of July 2019, only Truvada (emtricitabine/tenofovir disoproxil fumarate) has been approved by the FDA for PrEP in the U.S. Descovy (emtricitabine/tenofovir alafenamide fumarate) was approved for the treatment of HIV infection in 2016 and has been studied for use as a PrEP agent since that time. In an early report of results from the DISCOVER trial in March 2019, Descovy was shown to be non-inferior to Truvada for preventing HIV infection. FDA is now reviewing those results and other data in determining whether Descovy will be approved as a second agent for use in preventing HIV in the U.S. Your use of Descovy would be considered “off-label” for PrEP, since Descovy is approved for treating HIV infection but not yet approved to prevent HIV infection.”

Inclusion for emtricitabine/tenofovir alafenamide for PrEP

1. Reported or observed renal toxicity or bone mineral density loss
2. eGFR >30 mL/min
3. Ongoing risk of acquiring HIV infection

Clients may be initiated on emtricitabine/tenofovir alafenamide fumarate at their enrollment visit based on history of renal or bone impairment. A trial of emtricitabine/tenofovir disoproxil fumarate is not needed if the clinician and client prefer to immediate start on emtricitabine/tenofovir alafenamide fumarate.

Clients with a creatinine elevation on emtricitabine/tenofovir disoproxil fumarate and are switching to emtricitabine/tenofovir alafenamide fumarate must be monitored per protocol until their creatinine is 10% of baseline prior to returning to the routine follow-up schedule.

The follow-up schedule for those on emtricitabine/tenofovir alafenamide fumarate remains unchanged per protocol. Clients with creatinine elevations on emtricitabine/tenofovir disoproxil fumarate and are switching to emtricitabine/tenofovir alafenamide fumarate must be monitored per protocol until their creatinine is 10% of baseline prior to returning to the routine follow-up schedule. While creatinine monitoring is not required for use of emtricitabine/tenofovir alafenamide fumarate, it will be obtained for additional monitoring during off-label use for PrEP.

Emtricitabine/tenofovir alafenamide fumarate is not recommended for and should not be used for PrEP 211 dosing, pending further study.

References:

Hare, 2019 <http://www.croiconference.org/sessions/phase-3-discover-study-daily-ftaf-or-ftdf-hiv-preexposure-prophylaxis>

Gilead, March 6, 2019

<https://www.gilead.com/news-and-press/press-room/press-releases/2019/3/gilead-announces-data-demonstrating-noninferiority-of-oncedaily-descovy-vs-oncedaily-truvada-for-prevention-of-hiv-infection>

Lamivudine and tenofovir disoproxil fumarate as PrEP:

Clients who have difficulties accessing Truvada (emtricitabine/tenofovir disoproxil fumarate) due to insurance or financial costs issues may be dispensed:

- tenofovir disoproxil fumarate 300mg 1 tablet by mouth daily for PrEP with lamivudine #90
- lamivudine 300mg 1 pill by mouth daily for PrEP with tenofovir #90

The use of lamivudine is off-label but lamivudine is considered an acceptable alternative to emtricitabine by the WHO. Clients are to be counseled around the data supporting this alternative medication for PrEP.

References

<https://apps.who.int/iris/bitstream/handle/10665/273934/WHO-CDS-HIV-18.22-eng.pdf>

Time and Events:

	Screen	Day 3	Month 1	Q3 Months	Q12 Months	Creatinine Elevation	Termination
<i>Age</i>	X						
<i>Address</i>	X		X	X			
<i>Gender at Birth</i>	X						
<i>Identified Gender</i>	X						
<i>HIV Risk Assessment</i>	X						
<i>PrEP Consent</i>	X						
<i>Acute Viral Syndrome</i>	X		X	X			X
<i>Physical Exam</i>	X						
<i>Health History</i>	X		X	X			
<i>RX Provided</i>	X		X	X			
<i>HIV/STI Counseling</i>	X		X	X			
<i>STI Screen</i>	X		X	X			
<i>Rapid HIV Rapid AB</i>	X		X	X**			
<i>HIV pooled RNA</i>	X*		X	X			
<i>4th Gen HIV Antibody</i>					X		
<i>HBV AG</i>	X						
<i>HCV AB</i>	X						
<i>Urine Pregnancy Test, if applicable</i>	X		X	X			
<i>GFR/Creatinine/Bun</i>	X		X	X		X	
<i>Cystatin C</i>						X	
<i>AST/ALT/ALP</i>	X						
<i>Glucose</i>	X						
<i>Urine Pregnancy (if applicable)</i>	X		X	X			
<i>Adherence Counseling</i>	X		X	X			
<i>Adherence Measure</i>			X	X			
<i>PrEP Counseling</i>	X		X	X			
<i>Stigma Counseling</i>	X		X	X			
<i>Benefits Navigation</i>	X		X	X			
<i>Phone/Pharmacy Check In</i>		X					
<i>Reason for Termination</i>							X
<i>PrEP Seroconversion Labs</i>							X

***Order individual HIV RNA if treating for presumptive HIV**

****Clients who report full adherence and no sexual contact off PrEP do not require a rapid HIV Antibody test at routine follow ups.**

PrEP Consent

I understand that I will be evaluated to see if Truvada for PrEP is appropriate for me and I may not be eligible for Truvada if I have certain medical conditions.

I understand that Magnet can only provide an evaluation for Truvada for PrEP. Magnet will assist me in obtaining coverage for the medication but they cannot guarantee access to the medication if there are certain financial hurdles or eligibility limitations to assistance programs.

I understand that while Truvada for PrEP can be highly effective at preventing HIV infection, there is still a chance that I can get HIV even if I take my pills every day.

I understand that Truvada for PrEP does not prevent syphilis, gonorrhea, chlamydia, hepatitis B or C, or pregnancy. Truvada for PrEP is just a part of my comprehensive sexual health strategy that includes other risk reduction strategies that are appropriate for me.

I understand that I need to have my health monitored while on Truvada for PrEP and I will do my best to attend my follow up appointments