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	Policy Section: Patient Care
Non-Occupational Post Exposure Prophylaxis Program	

Back ground: The most effective means of preventing HIV infection is by preventing the initial exposure through the use of risk reduction strategies such as the use of PrEP, barrier methods, and harm reduction strategies such as seropositioning. Despite these interventions, HIV infections may still occur. In 2001, the U.S. Department of Health and Human Services (DHHS) Working Group on Nonoccupational Postexposure Prophylaxis made a recommendation to provide non-occupational postexposure prophylaxis (nPEP) to clients who were exposed to HIV <72 hours.

In occupational settings, the provision of PEP after an exposure can reduce the risk of transmission by 81%. The rates of reduction of transmission of nPEP is not well studied. Assuming the risk reduction for PEP and nPEP are equal, the use of nPEP can have a improved cost per quality-adjusted life year in men who have had condomless anal receptive intercourse. The following protocol is adapted from the CDC recommendations based on this data.

Client Eligibility for Services: Due to the urgency of accessing treatment, all clients who present to SFAF will be eligible for nPEP services regardless of where they live.

Healthy Clients: Due to the limited ability to provide comprehensive primary care at SFAF, Clients must be in good health to be enrolled in the nPEP 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 SFAF.

Scope of Care: Clients presenting to the nPEP program are not required to have a primary care provider to access nPEP. SFAF will provide care and monitoring related to nPEP 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. SFAF will prescribe medication for nPEP as well as those medications required to manage side effects related to nPEP use.

Immediate nPEP provided before medical evaluation: The immediate initiation of nPEP after an exposure to HIV may increase the efficacy of the treatment. There are clinical situations where completing the full nPEP evaluation may cause significant delays to initiating nPEP.

If, by the determination of the clinician, the delay in completing an nPEP evaluation could impact the efficacy nPEP, the RN/NP/MD may initiate nPEP immediately in the clinic after completing the immediate nPEP screening. This brief screening is meant to ensure the safety of providing immediate nPEP and is not meant to replace the complete evaluation.

The RN/NP/MD may provide the initial dose of medication if the following immediate nPEP screening is all answered no.

1. Assessment of the exposure is determined to be high risk per nPEP protocol.
2. Record drug allergies.

After completion of the screener, the RN/NP/MD will administer

1. douletegravir 50mg take 1 pill by mouth now
2. emtricitabine/tenofovir 200mg/300mg take 1 pill by mouth
   or
3. bictegravir/emtricitabine/tenofovir 50mg/200mg/25mg take 1 pill by mouth

If the client reports a medical history that necessitates further evaluation or an alternative regimen, the complete nPEP evaluation must be completed.

After the provision of immediate nPEP, the complete nPEP evaluation should be completed within 24 hours.

Complications
The complete nPEP evaluation may reveal some medical conditions where the administered medication may be contraindicated or administered with caution.

If the client if found to be HIV positive at the evaluation, the regimen should be intensified with darunavir 800mg/cobicistat 150mg, bictegravir/emtricitabine/tenofovir 50mg/200mg/25mg until the client can be linked into care. 6ml of EDTA plasma should be collected and frozen to obtain an HIV viral load and Genotype.

If the client is found to have Hepatitis B, the client should remain on emtricitabine/tenofovir 200mg/300mg and be linked to specialized care. The medication should not be stopped without proper medical evaluation.

If the client is found to have renal insufficiency with an eGFR <50, the clinician should follow the renal dosing guidelines in this protocol.

Screening and Enrollment into the nPEP Program:
All parts of the screening visit and enrollment must be completed prior to initiation of nPEP.

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

1. During a routine HIV/STI screening visit, the counselor and the client may identify an exposure to HIV that has occurred within 72 hours.
2. A client may have already identified the potential need for nPEP prior to the visit.

Sexual Assault: All clients requesting nPEP must be assessed for sexual assault. If a sexual assault has occurred, the clinician will follow the sexual assault protocols.

nPEP Enrollment: The nPEP enrollment can be completed in two 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 nPEP Program intake involve:

1. Registration paperwork

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

NP/MD path: The NP/MD path involves the NP/MD completing the baseline nPEP Eligibility form, collecting the health history, reviewing the medications, performing a physical exam, reviewing the point of care tests, determining eligibility for nPEP, 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 nPEP 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 PEP, and write a prescription.

License required for each step

	HIV Counselor	**RN**	**NP/MD**	**Benefits Counselor**
HIV/STI Visit	X			X
nPEP Eligibility		X	X	
Health History		X*	X	
Medications		X*	X	
Physical Exam			X	
Lab Tests		X	X	
nPEP Assessment		X*	X	
nPEP Counseling		X	X	
Adherence		X	X	
Prescription			X	
Benefits Counseling		X	X	X
PCP Notification		X	X	X
PrEP Health Program		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 nPEP Consent.

HIV/STI Testing: The initial screening 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 nPEP visit

nPEP Eligibility: A PEP eligibility tool adapted from CDC guidelines will be used to determine the appropriateness of nPEP Program provided by SFAF.

Eligibility Criteria

1) Age 12 and Over
2) HIV Negative
3) High risk exposure for HIV (should meet one criteria)
    a. Condomless anal/vaginal receptive intercourse with someone of unknown or detectable viral load
    b. Shared needle
    c. Condomless insertive anal intercourse with someone of unknown or detectable viral load
4) Low Risk Exposure
    a. Oral sex with someone of unknown or detectable viral load
    b. Any sex with an HIV-infected partner with an undetectable viral load

Exclusion Criteria

1) The fixed-dose combination elvitegravir/cobicistat/tenofovir/emtricitabine and emtricitabine/tenofovir should not be initiated in patients with CrCl <60 mL/min and should be discontinued in those with CrCl <50 mL/min. bictegravir/emtricitabine/tenofovir 50mg/200mg/25mg should not be initiated in patients with a CrCL<30ml/min.
2) Abnormal screening labs not explain by comorbid condition
3) Any other conditions that are deemed contraindicated for nPEP by the NP/MD

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 focused physical exam will be completed

Lab Tests: A comprehensive medical panel, Hepatitis B AG, Hepatitis C AB, and rapid HIV/RNA will be collected for the initial evaluation. A urine pregnancy test will be collected for clients of child bearing capacity. nPEP may be initiated with the Hepatitis AG and RNA pending. Renal and liver function tests should be within normal limits unless explained by a known health condition that is not contraindicated.

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

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

1. nPEP 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 nPEP management.

nPEP Counseling: Providers will discuss the risks and benefits of nPEP. The benefit of nPEP includes a reduced risk of HIV infection. The chances of HIV infection are related to how soon after the exposure nPEP was initiated and how well the client is able to adhere to the nPEP regimen. The risks of nPEP include the medication side effects.

Adherence Counseling: A brief interactive counseling session will be conducted to highlight possible short term side effects of oral Stribild, including nausea, abdominal cramping, and headache. The importance of adherence for obtaining the benefits of nPEP 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. Elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild) can be taken any time during the day, at different times on different days, and with 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 limitations of nPEP will also be discussed, including that benefits require daily adherence, and that nPEPdoes not prevent STI's other than HIV (including syphilis, herpes, GC/CT, HBV, HPV, and HCV) and does not prevent pregnancy. 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 nPEP 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?

The following treatment recommendations of based on the easy access to the patient assistance program. Other medications may be used if easily accessible.

Risk Exposure: All clients with a HIGH exposure who are deemed eligible by the NP/MD and have completing the adherence and nPEP counseling will receive a written 28-day prescription for elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild) or emtricitabine/tenofovir (Truvada) with Dolutegravir (Tivicay). Clients with existing renal disease or medication contraindications related to Stribild will receive Truvada and Tivicay. Clients with renal insufficiency may receive emtricitabine/tenfovir, at the renal dosing of every other day and Douletegravir 50mg . SFAF will provide a full 28 course of nPEP and not use starter packs. Clients with a low risk exposure but have symptoms of acute HIV should receive a 3-drug regimen to cover possible acute HIV that occurred outside of the 72 hour window.

All clients with a low risk exposure should be counseled on sexual exposure and encouraged to close out the testing window for the exposure. The NP/MD may provide nPEP to a low risk exposure if the clinician decides it is medically warranted.

Recommend Treatment	High Risk
eGFR >50	elvitegravir, cobicistat, emtricitabine, tenofovir 1 by mouth daily for 28 days or Emtricitabine/Tenofovir 1 by mouth daily for 28 days AND Dolutegravir 50mg 1 by mouth daily for 28 days Or bictegravir/emtricitabine/tenofovir 50mg/200mg/25mg 1 by mouth daily for 28 days
eGFR <50	bictegravir/emtricitabine/tenofovir 50mg/200mg/25mg 1 by mouth daily for 28 days

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 nPEP at a reasonable costs.

Notification of client's PCP: Once a client has been enrolled in the nPEP program, a standard letter outlining the client's enrollment into SFAF's nPEP program will be sent to the client's primary care provider, if there is one. Consent will be obtained from the client in order to contact the Primary Care Provider. 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.

Follow-up visits: Those electing nPEP should return for follow-up at month 1 and week 6. If the client elects to enroll in the PrEP Health Program, the follow up visits will be done as part of the PrEP Health Program.

Follow-up Events and RN Management Orders:

Elevated creatinine: Upon completion of nPEP and prior to initiation of PrEP (if elected), a creatinine will be obtained. If abnormally elevated or elevated more than 50% above baseline, creatinine testing should be repeated on a separate specimen from the same visit. If the elevation in serum creatinine is confirmed, PrEP should be delayed. Serum Creatinine should be repeated every 2 weeks until the serum creatinine resolves to the normal range or to within 10% of the baseline value. Once the serum creatinine resolves, sexual risk will be assessed and starting PrEP will be recommended in those who have on-going risk factors **or an expressed desire to start.** Serum creatinine will be rechecked monthly for the 3 months after restarted then every 3 months with routine visits.

Seroconversion or NAT positive procedures: While nPEP may prevent some HIV infections, some clients may still seroconvert. Anyone who develops a reactive HIV antibody test or detectable HIV nucleic acids will be immediately linked to care and offered counseling. Clients should remain on nPEP until they are linked to care.

Nausea or vomiting or headaches: Gastrointestinal side effects and head aches have been reported with elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild), douletegravir, emtricitabine/tenofovir, and bictegravir/emtricitabine/tenofovir. These side effects are generally self-limiting and resolve within 2 weeks initiating the regimen. If a client reports nausea or vomiting the client will be encouraged to take the medication at night or with non-spicy food. If the nausea, vomiting, or headaches persists after 2 weeks, nPEP should be reevaluated. OTC PPIs if not contraindicated may be recommended to alleviate GI side effects.

Abnormal dreams: Abnormal dreams have been reported with the use of elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild).. 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: Bone loss resulting from short-course elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild) therapy is unlikely in the absence of pre-existing disease. If the client reports any suspicious fracture, further work-up is indicated, and discontinuation of elvitegravir, cobicistat, emtricitabine, tenofovir (Stribild) should be considered in that context.

GC/CT/Syphilis: nPEP does not provide any protection against other STIs. If a client reports multiple STI infections, this is not a reason to discontinue nPEP. All new STI infections will be treatd independent of nPEP therapy. The client will receive appropriate sexual risk reduction counseling and encouraged to notify sexual partners.

*Pregnancy***:** Clients of child bearing potential will be given a urine pregnancy test at baseline and at the 1 month follow up. If the urine pregnancy test is positive, the client should be referred to an OB/GYN. nPEP may be provided to a pregnant client with the guidance of an OB/GYN. bictegravir/emtricitabine/tenofovir has no pregnancy data. Douletgravir has been linked to neural tube defects and should be avoided in early pregnancy. Emtricitabine/tenofovir is safe to use in pregnancy. Elvitegravir/cobicistat/emtricitabine/tenofovir and emtricitabine/tenofovir is a category B pregnancy medication . All pregnancies on ARV should be reported to the Pregnancy Registrar at 1-800-258-4263

Terminating nPEP: Clients may stop nPEP at any time though they should be encouraged to complete the 28 days. Alternatives should be offered if the client is having trouble with side effects before electing to stop completely. nPEP may also be stopped if the source of the exposure has been confirmed to be HIV-negative, and no other high-risk exposure episodes have occurred, during the follow up period. Clients terminating nPEP early may enroll immediately into the PrEP Health Program.

Time and Events:

	Enrollment	Month 1	Week 6	Termination
Age	X			
Address	X	X	X	
Identified Gender	X			
HIV Risk Assessment	X			
nPEP Consent	X			
ARS Symptom Check	X	X	X	X
Physical Exam	X			
Health History	X			
Medications	X			
HIV/STI Counseling	X	X	X	
STI Screen	X			
HIV AB/RNA	X	X	X	
Urine Pregnancy Test	X			
HBV AG	X			
GFR/Creatinine/Bun	X	X		
AST/ALT/ALP	X	X		
Glucose	X	X		
Urine Pregnancy (if applicable)	X	X		
Adherence Counseling	X		X	
Adherence Measure		X	X	
nPEP Counseling	X			
Benefits Coordination	X			
Reason for Termination				X
PrEP Health Program		X		

nPEP Consent

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

I understand that SFAF can only provide an evaluation for nPEP. SFAF 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 my provider will review the potential side effects of nPEP medications including but not limited to kidney problems, bone loss, nausea, and vomiting.

I understand the sooner I start taking my medication after an exposure to HIV the better it will work. nPEP does not prevent exposures that occurred more than 72 hours ago.

I understand that while nPEP 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 my ability to take my pills every day is related to how well nPEP will work for me. The better I am at taking my pill every day the more protection I will have against HIV.

I understand there are some medications I shouldn't be taking with nPEP and I will notify SFAF of any changes in the medications I take.

I understand that I will be screened for hepatitis B. If I have hepatitis B, I may need to stay on nPEP for many years.

I understand that nPEP does not prevent syphilis, gonorrhea, chlamydia, hepatitis B or C, or pregnancy.

I understand that I need to have my health monitored while on nPEP and I will do my best to attend my follow up appointments.