Virginia Department of Health –Division of Disease Prevention: nPEP Protocols for Local Health Department

I. Summary: Purpose of nPEP

Non-Occupational Post-Exposure Prophylaxis (nPEP) is an emergency antiretroviral treatment used to reduce the likelihood of establishing an HIV infection after a potential exposure via a person of unknown HIV status or person who is HIV positive, through non-occupational means, including:

- Receptive or insertive anal sex
- Receptive or insertive vaginal sex
- Sharing injection drug equipment

nPEP must be taken within 72 hours of potential exposure and is not intended for ongoing use.

Historically, nPEP has been solely prescribed for victims of sexual assault. **However, recently updated guidelines from the Centers for Disease Control indicate that nPEP may also be prescribed after any encounter that may result in HIV transmission. Encounters include, but are not limited to, condomless sex, needle sharing, or sharing other drug paraphernalia.**

As a secondary prevention measure, nPEP is not intended to be an individual's only prevention method. Consistent condom use, using clean unshared needles, and other prevention measures should be practiced correctly and consistently while the patient is on nPEP and after the course of medication. Providers should discuss the aforementioned primary prevention methods, as well as use of PrEP (Pre-Exposure Prophylaxis) for long term prevention of HIV, Hepatitis C, and other sexually transmitted or blood borne diseases. Inability to practice these behaviors correctly or consistently does not exclude a person from being prescribed nPEP, but does offer an opportunity to further discuss risk reduction and primary prevention.

General Information:

nPEP is a 28-day regimen, typically consisting of Tenofovir 300 mg PO daily + Emtricitabine 200 mg PO daily plus Raltegravir 400 mg PO twice daily or Dolutegravir tab 50 mg PO once

daily. This dosage is subject to change for patients under 18 years old, based on weight, and those with compromised kidney function.
Prior to beginning nPEP, medical staff will need to know all medications the patient is currently taking to see if there are any drug-drug interactions that may occur or interfere with the nPEP course of treatment. **Patients may initiate nPEP treatment without yet having lab results or knowing the HIV status of themselves or person-source of exposure, as nPEP must be initiated as soon as possible within 72 hours of exposure.** Testing using fourth-generation EIA or HIV RNA assay should be conducted as soon as possible, before or after initiation of treatment. Patients must also undergo several other lab tests, including tests to measure kidney and liver function, Hepatitis B and C tests, chlamydia, gonorrhea, syphilis tests, and a pregnancy test (if applicable). If the HIV test result for the individual receiving treatment is HIV positive, the patient should cease nPEP treatment immediately and be referred to a provider for HIV management.

If possible, testing for the person-source should also be conducted. If person-source's HIV test result is negative, providers should consult with the patient to determine if continued treatment is appropriate. Situations which may warrant continuation of nPEP, include if it is possible the person source is sero-converting or if there were other potential exposures within the 72-hour window prior to treatment.

In 2016, the Centers for Disease Control and Prevention (CDC) released its updated guidelines for the use of nPEP for the prevention of HIV infection. The following CDC documents are available:

- *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV- United States, 2016* (http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf)
- *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2014* (http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf)
- These protocols are intended to serve as a guide for personnel and providers administering nPEP. These protocols are based on the CDC guidelines above, along with the following New York City State Department of Health AIDS Institute's resources:
- *HIV Clinical Resource : HIV Prophylaxis Following Non-Occupational Exposure* (http://www.hivguidelines.org/wp-content/uploads/2016/03/nPEP_for-PDF_11-29-14.pdf)
- *HIV Clinical Resource : HIV Prophylaxis for Victims of Sexual Assault* (http://www.hivguidelines.org/wp-content/uploads/2014/10/hiv-prophylaxis-for-victims-of-sexual-assault.pdf)

II. Eligibility:

PATIENT MUST:

- be 18 years or older
    - if younger than 18, must have consent from parent or legal guardian OR be an emancipated minor
- be a Virginia resident, if state funding is necessary for prescription and/or lab work funding assistance
- **in the last 72 hours,** have been exposed to blood, genital secretions, or other potentially infected body fluids of a person known to be HIV infected or of unknown HIV status when that exposure represents a substantial risk for HIV acquisition

AND

- Determination of the prescribing medical provider based on best-evidence for use of nPEP as an HIV secondary prevention tool for an HIV negative person, or with unknown status.

DDP provides nPEP to both insured and uninsured residents of Virginia at no cost. Uninsured individuals may receive the full 28-day course of medication, provided they meet programmatic guidelines outlined below. Insured individuals may receive up to a five-day supply of medication. This is intended to expedite access to the medication while the individual navigates insurance or patient assistance programs.

III. Patient Education and Resource Navigation:

It is important to provide patients with comprehensive education as to the function, effectiveness, and risks of nPEP before treatment, and provide ongoing patient support during the 28 day course. Clinical staff should provide information on all physical and mental health options that are available to help ensure adherence and reduced risk. Appendix A provides a comprehensive list of discussion points and psycho-social factors to discuss with patients.

Patient Education and Informed Decision Making Help

Patient education is critical to shared decision-making and the success of nPEP as part of the secondary prevention plan. Patient education also sets the stage for further primary prevention. Medication adherence may be improved when patients participate in treatment decisions.

Patient should be informed of:

1. How nPEP works

2. Limitations of nPEP
3. Potential side effects associated ARV treatment
4. Long-term safety of nPEP
5. Symptoms of sero-conversion
6. Importance of daily adherence for the full 28 days
7. Note for those who may be pregnant: There have been no studies that have looked directly at the impact of nPEP on a developing fetus; however, nPEP has been shown to provide protection against HIV infection to both the mother and the fetus

Providers should work to ensure that patients understand how nPEP works, including the risks and benefits, and the need for strict adherence. Explanations should be given in the patient's native language and should be easy to understand.

> For example: *The medications prescribed for nPEP are drugs that are commonly used to treat HIV in persons who are HIV-positive. Following an exposure to HIV, when taken daily by people who are HIV-negative, they help the body fight off an HIV infection. The pill needs to be taken every day twice a day in order for the body to build up strong enough drug levels to block HIV. It cannot be expected to work if it is taken inconsistently, or not taken the full 28 days. nPEP reduces, but does not eliminate, HIV transmission risk. You should use condoms and clean drug works while on nPEP. Also, nPEP does not protect against other sexually transmitted or blood-borne diseases. If you feel like you might need to take nPEP again, you might want to consider going on PrEP, which is only one pill a day, and is more suitable for longer term use.*

Providers should obtain a sexual and drug-use history, and discuss risk-taking behaviors with their patients. In cases of sexual assault, use additional care when discussing risk factors, and provide information on supportive services for sexual assault survivors. **Screening functions as a tool for patients and providers to better discuss risk and the evidence-based prevention methods that are available to meet patient needs.** Providers should present patients with all applicable safer sex practices and safer injection techniques, and assist patients in planning future primary prevention. This discussion should include PrEP if the patient's exposure factors are persistent and demonstrate any of the following high-risk behaviors:

Applicable High-Risk Behaviors Include:

- Men who have sex with men who engage in unprotected anal intercourse
- Individuals who are in a sero-discordant sexual relationship with a known HIV-infected partner
- Male to female and female to male transgender persons engaging in high-risk sexual behaviors
- Individuals engaging in transactional sex, such as sex for money, drugs or housing, or those working in the commercial sex industry, such as pornographic film actors/actresses

- Injection drug users who report any of the following behaviors: sharing injection equipment and/or works, injecting one or more times daily, injecting methamphetamines, engaging in high-risk sexual behavior
- Individuals diagnosed with at least one anogenital sexually transmitted infection in the last year, who still practice high risk behaviors
- Individuals who have been prescribed nPEP more than once

Patients may begin taking PrEP immediately at the conclusion of a 28 day course of nPEP treatment, pending negative HIV test results.

Physician Resources and Informed Care Support:

In 2016, the Centers for Disease Control and Prevention (CDC) released its updated guidelines for the use of nPEP for the prevention of HIV infection. The following CDC documents are available:

- *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV- United States, 2016* (http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf)
- *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2014* (http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf)

These protocols are intended to serve as a guide for personnel and providers administering nPEP. These protocols are based on the CDC guidelines above, along with the following New York City State Department of Health AIDS Institute's resources:

- *HIV Clinical Resource : HIV Prophylaxis Following Non-Occupational Exposure* (http://www.hivguidelines.org/wp-content/uploads/2016/03/nPEP_for-PDF_11-29-14.pdf)
  HIV Clinical Resource : HIV Prophylaxis for Victims of Sexual Assault (http://www.hivguidelines.org/wp-content/uploads/2014/10/hiv-prophylaxis-for-victims-of-sexual-assault.pdf)

PLEASE NOTE: The Centers for Disease Control has issued an Interim Statement Regarding Potential Fetal Harm from Exposure to Dolutegravir Implications for HIV Post-exposure Prophylaxis (PEP)

> A preliminary unscheduled analysis of data from an ongoing NIH-funded observational study in Botswana suggests that an increased risk of neural tube defects was associated with exposure to antiretroviral (ARV) regimens that include dolutegravir (DTG) at conception.

CDC makes the following interim recommendations for the use of HIV PEP (occupational or nonoccupational) while the agency prepares a more detailed review of the evidence and recommendations.

> Health care providers prescribing PEP should **avoid use of DTG for:**
> • **Non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method; and,**
>
> • **Pregnant women early in pregnancy** since the risk of an unborn infant developing a neural tube defect is during the first 28 days.

More information, including the complete CDC Post-Exposure Guidelines, is available at

https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf (Non-Occupational PEP)

IV. Clinical Screening

Diagnostic Baseline Screening test required:

Baseline Tests:	***Name of Test and Cost:***	***Comments and Rationale***
HIV Test: 4th generation or RNA PCR testing		Test for acute HIV infection in ALL patients initiating nPEP with a 4th Generation combination HIV Ag/AB assay. Screen for acute HIV infection symptoms. If patient has chronic HIV infection, nPEP is not appropriate treatment. The risk of developing resistance to this classification of drugs (nucleoside analog reverse transcriptase inhibitor) is high.
Serum creatinine		CrCl should be ≥ 60 ml/min (Cockcroft Gault) to safely use tenofovir. eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).
Alanine transaminase, aspartate aminotranferase		High dose ARV medication can impact liver function, this is particularly important to monitor for those with HBV or HCV.

Hepatitis B surface antigen Hepatitis B surface antibody Hepatitis B core antibody		Patients with chronic HBV **can** use nPEP medications, but should consult with doctor to assess liver function during and after 28 day regimen. Also, caution the patient that rebound viremia may occur after discontinuing nPEP. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
Hepatitis C antibody test		Delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and HCV infection.
STDs (based on patient's self-reported sexual history)		Participants should be tested for syphilis, urethral, rectal and pharyngeal GC and CT unless contraindicated by risk profile.
Pregnancy test (if applicable)		nPEP should be coordinated with pre-natal care.

A complete list of the patient's current medications should be made before initiating nPEP. Patient use of medications that reduce kidney renal function or compete for active renal tubular secretion should be considered before prescribing nPEP. Monitor these patients for dose-related renal toxicities.

Follow-up recommendations:

- Weekly follow-up either over the phone or in-clinic are recommended during the 28 day treatment to ensure adherence and check for side effects or other health concerns related to treatment
- HIV Ag/Ab testing is recommended 4-6 weeks after exposure, and again after 3 months
- HBV and HCV tests are recommended at 6 months post-exposure
- Syphilis testing is recommended 4-6 weeks after exposure and at 6 months post-exposure
- Chlamydia and gonorrhea testing are recommended 4-6 weeks after exposure if patient is symptomatic, or if testing was not done at baseline

Other important considerations when prescribing nPEP:

- **Is the patient pregnant or attempting to conceive?**
    - There have been no studies that have looked directly at use of nPEP during pregnancy. However, there have been multiple studies on the use on various antiretroviral therapies used during pregnancy by HIV positive people. According to the CDC, "no severe side effects, toxicity, or adverse pregnancy outcomes have been reported to occur among HIV-uninfected women taking antiretrovirals for oPEP or nPEP."

- Ask all patients who are able to conceive about pregnancy status, and advise pregnant patients on additional risks and benefits of nPEP during pregnancy.

- **Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?**
  - Obtain a thorough medication history and consult the medication package insert for additional information on drug interactions

- **Does the patient have osteopenia/osteomalacia/osteoporosis?**
  - There may be a risk of bone loss associated with tenofovir. Though the duration of nPEP is brief, the dosage is high. Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis /osteomalacia/ osteopenia.

- **Is the patient an adolescent?**
  - nPEP is approved for use by individuals younger than 18 years old younger with the consent of their legal guardian or if the individual is an emancipated minor
  - Medication and dosage for those younger than 18 may be different that adult dosage based on age and weight of patient (see below chart for Truvada, Isentress and Tivacay information)
  - VDH Central Pharmacy is able to fill pediatric doses, though slower delivery is expected and greater coordination is needed with the pharmacy

Truvada dose is weight-based. It is <u>not</u> indicated in pediatrics weighing less than 17 kg.

Weighing 35 kg or more	Truvada 200/300 mg once daily	Stocked in pharmacy
Weight 28 to less than 35 kg	Truvada 167/250 mg once daily	*Dosage available, but not stocked in pharmacy*
Weight 22 to less than 28 kg	Truvada 133/200 mg once daily	*Dosage available, but not stocked in pharmacy*
Weight 17 to less than 22 kg	Truvada 100/150 mg once daily	*Dosage available, but not stocked in pharmacy*
Weighing less than 17 kg	Use has not been evaluated; do not administer	

Isentress is indicated in patients 4 weeks and older weighing at least 3 kg; dose is weight-based. It is <u>not</u> indicated in pediatric patients younger than 4 weeks.

Weight 25 kg or more	Isentress 400 mg twice a day	Stocked in pharmacy *(chewable available and may be preferred for this population but this formulation is not stocked in pharmacy)*
Weight 20 - <25 kg	Isentress 150 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy*
Weight 14 - <20 kg	Isentress 100 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy (oral suspension form not available)*
Weight 11 - <14 kg	Isentress 75 mg twice a day	*Dosage available with chewable tablets but not stocked in pharmacy (oral suspension form not available)*
Weight 8 - <11 kg	Isentress 60 mg twice a day	*Oral suspension not available*
Weight 6 - <8 kg	Isentress 40 mg twice a day	*Oral suspension not available*
Weight 4 - <6 kg	Isentress 30 mg twice a day	*Oral suspension not available*
Weight 3 - <4 kg	Isentress 20 mg twice a day	*Oral suspension not available*

Tivicay is indicated patients 12 years and older weighing at least 30 kg. It is <u>not</u> indicated in pediatric patients younger than 12 years of age or less than 30 kg.

30 to less than 40 kg	35 mg once daily	
40 kg or greater	50 mg once daily	*Stocked in pharmacy*

V. nPEP Timeline and Management

Prescription of nPEP should be provided as soon as possible, and fill requests should be made immediately to ensure that patients are able to begin treatment as soon as possible. **Patients must begin nPEP within 72 hours of exposure to be effective.**

At initial visit:
- Discuss nPEP use; clarify misconceptions, emphasize that patient must maintain use for full 28 days, twice a day, at the same time each day

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Prescribe 28-day supply of nPEP
- Follow up weekly to assess side effects, and adherence, either in person or by phone
- Discuss test results with patient, and advise both on results' potential impact on treatment, and follow-up care needed for any diagnoses made
- **If HIV test results are positive, discontinue nPEP**

4 to 6 week-up follow-up

•Provide all recommended tests and follow-up accordingly

•Conduct further risk assessment with patient

If exposure risk recurrent, discuss risk reduction plan including PrEP

Though nPEP and PrEP cannot be taken at the same time, a patient may initiate PrEP treatment immediately after 28 day course of nPEP

3-month visit and 6-month visits

- Provide additional testing per CDC guidelines:
  - HIV Ag/Ab testing again at three and six months post-exposure
  - HBV and HCV tests are recommended at 6 months post-exposure
  - Syphilis testing at 6 months post-exposure
- Continue to work with patients to discuss any ongoing exposure risks and risk reductions strategies such as use on PrEP

VI. Adherence Counseling

nPEP only is effective as a post-exposure tool to fight acute HIV infection if the patient takes the medication as prescribed for 28 days.

Though nPEP is not a long term commitment, helping the patient form strategies that ensure adherence may be useful. Strategies may include formulation of a patient-centered adherence plan, which accounts for times of day to take the drug, storage, what to do if the patient misses a dose, and what to do if side-effects occur. Adherence is often compromised by other factors such as mental illness, substance use, lack of stable housing, and interpersonal violence. Clinical staff and the patient should discuss barriers to adherence and possible means of overcoming these

barriers prior to the patient being prescribed nPEP. More information on talking to the patient about these topics can be found in Appendix A.

Linkage to services offered by community-based organizations (CBOs) or other service organizations may provide interventions that may help increase patient adherence. If the clinical staff feels these linkages may be useful to the patient, a referral can be made to CBOs (see resource list). DDP's HIV/STD/Hepatitis Hotline is also available to provide adherence counseling and resources for patients on nPEP.

VII. Prescription and Pharmacy Procedures

Due to the time sensitivity of nPEP, it is important to move quickly to have the prescription filled and received by the patient within 72 hours of the exposure. Please contact Virginia Department of Health (VDH) staff **(please see the table below for contact information)** as soon as possible to: ensure that all required information is collected from patient, clarify timeline, and be sure that the patient will be able to receive the medication within the window period. In the event that it is not possible have the medication shipped and received within the 72-hour window, VDH will discuss other options with clinical staff or patient.

Prescriptions for nPEP may come from a local health department (LHD) or any clinical practice, including a walk-in clinic, private practice, or emergency room; however, for purposes related to funding, it is important to know the source of the prescription. Because of the urgent nature of the nPEP all related processes can and should be done via telephone. Please call 804-864-7938 to complete the application process.

The following patient information is required:

- Full legal name
- **Date and time of exposure**
- Sex at birth
- Gender identity
- Date of birth
- Phone number and if we are able to leave voice mail
- Home address
- Mailing address, if different than home address
- Race
- Hispanic or Latino ethnicity
- Name and address of LHD for medication to be sent

- Contact information for both the prescriber and pick-up LHD
- Type of exposure, if available

Once an telephone application is approved, VDH staff will notify the prescriber who should then call in verbal order Central Pharmacy at 804-371-0236. VDH staff will follow-up with Central Pharmacy to coordinate delivery to the LHD within the necessary time frame. If the prescription and application are received by 3 p.m. on a business day, it may be possible to have the medication shipped the same business day and received at the LHD the next business day. Otherwise, it will be shipped out the next morning and received at the LHD on the following business day.

If a patient will be picking up medication at an LHD that did not write the original prescription, it may be necessary to have medical records faxed to the health department. Patients should also be made aware of any procedures or registration required at the LHD, how long the process may take, as well any required documentation needed for pick-up. If any assistance is needed, please contact the program support specialist. When the patient picks-up the medication, the patient should sign the Medication Order Form and clinical staff should review CDC follow-up recommendations with the client. LHD staff will then fax the Medication Order Form to VDH.

If the program support specialist is not available, please contact the PrEP Coordinator, Eric Mayes at 804-864-7335. If neither is available, call the Disease Prevention Hotline 800-533-4148 for further assistance.

Important Numbers

Program Support Specialist, Maurice May	804-864-7938
PrEP Program Coordinator, Eric Mayes	804-864-7335
VDH Disease Prevention Hotline	800-533-4148
Central Pharmacy Phone	804-786-4326
Central Pharmacy Fax	804-371-0236
VDH Prevention Fax	804-864-8053

Review of Steps

- Upon patient receiving prescription, fill out application and fax to VDH
    - Please do not hesitate to reach out to VDH staff with questions, concerns, or special patient considerations
- Call program support specialist or other VDH staff to review application
- Upon approval of application, fax prescription and medication order form to Central Pharmacy
- VDH staff will follow-up on when to anticipate the medication arriving at the LHD

- LHD staff should communicate this with the patient, make them aware of any necessary processes for the client to receive the medication
- Have the client sign the medication order form and fax to VDH

VIII: Evaluation and Client Consent

DDP will regularly conduct evaluation in order to determine program effectiveness and to assist in similar future projects. Patients receiving DDP-funded medications must consent to be involved in the evaluation process. Other participants should be encouraged to participate in evaluation as well. This process involves:

1. Permission for LHD to share information on behavioral risks, HIV/STD/Hepatitis status, and drug adherence with VDH-DDP program staff
2. Completion of short follow-up and patient satisfaction survey (paper or online) at end of patient participation

X. Resources

DDP HIV STD HEPATITIS Hotline: 800-533-4148

VDH-DDP Contact Information:

General Program Support and Financial Qualification: Eric Mayes

HIV Prevention Director: Elaine Martin

Social Media Coordinator: Chris Barnett

APPENDIX A: Educational and Psychosocial Tools

Pre-Prescription: Education and Counseling:

Patients need to understand how nPEP works, including risks and benefits, the need for strict adherence to help the body fight infection, and what nPEP will and will not do for them. Explanations should be given in the patient's native language and should be easy to understand.

For example: n*PEP is a combination of pills that if taken twice a day by people who are HIV negative may prevent HIV infection after a person has been exposed to the virus. It has to be taken consistently – twice daily, at the same time each day. nPEP is most effective at preventing infection if taken consistently at the same times each day for the whole 28 days. nPEP reduces, but does not eliminate, the risk of getting HIV. While you are taking nPEP, you still need to use condoms, clean your works to prevent further exposure, and protect against other sexually transmitted diseases, Hepatitis C, which nPEP does not provide protection against.*

Checklist 1: Patient Education and Assessment

1. **How nPEP works:**
    - **a.** Explain how nPEP works in language that is easy to understand.

        (For example: *nPEP is a combination of several medications, that when taken twice a day, as prescribed, may prevent HIV infection after a potential exposure.*)

    - **b.** nPEP works is a secondary prevention tool, and should not serve as a patient's only prevention strategy; it is instead a part of a larger comprehensive plan. If risk of exposure is ongoing, encourage the patient to consider PrEP, condoms, and other primary prevention tools.

        (For example: *nPEP does not prevent other STI's and it is recommended that you still use condoms and/or clean injection equipment while on nPEP, as well as develop or assess current prevention plan to see if it fits current risks and needs*.)

2. **Limitations of nPEP:**
    - **a.** Efficacy is dependent on adherence.

        (For example*: nPEP ONLY helps prevent infection when taken consistently – twice daily as prescribed, at the same time each day*.)

    - **b.** nPEP reduces the likelihood of infection after an exposure, but does not eliminate risk of HIV infection entirely.

        (For example: *nPEP is still being studied and though a number of studies have shown that it prevents infection, several long term risks remain*

unknown. When initiated within 72 hours of exposure, and taken correctly and consistently over 28 days, nPEP has been shown to be 99 percent effective in preventing HIV infection.)

3. **nPEP use:**
    a. Dosing and need for daily adherence

    (For example: *nPEP is a 2-3 pill, twice a day regimen, which must be taken consistently over a 28 day period to be effective. Taking nPEP incorrectly could lead to resistance and other complication, so it's important that you take the pills as prescribed*.)

    b. When doses are missed

    (For example: *If doses are accidentally missed, do not double up doses, but do take the missed mediation as soon as you can, and maintain your pill schedule after that*.)

    c. Common side effects: About half of patients taking nPEP experience mild side effects in first two weeks of treatment. Side effects can include: Headache, nausea, fatigue, insomnia, skin sensitivity and rash. Side effects usually resolve or improve within the first two weeks.

    (For example: *nPEP does come with some side effects, but they are tolerable and usually diminish or disappear after a few weeks. Common side effects are: headache, nausea, fatigue*.)

    d. Baseline tests and schedule for monitoring

    (For example: *Upon being prescribed nPEP, your doctor will also want to run a series of medical tests including: an HIV test, liver and renal function tests. nPEP medications can impact liver and kidney function, and we want to be aware of any interactions nPEP may have with other medications or conditions you may have. If you test positive for HIV, you will need to discontinue use of nPEP and go on an ART regimen appropriate for management of infection*.)

    e. Elements of and schedule for follow-up monitoring, including HIV testing at 4-6 weeks, 3 months, and 6 months after exposure.

(For example: *nPEP is a 28-day prescription. At the end of 28 days you will need to come in so we can run tests again, including for HIV, to see if everything is going ok*.)

4. **Criteria for discontinuing nPEP**
   - **a.** Positive HIV test result:

     (For example: *If you test positive at any point in the 28 day treatment period, nPEP should be discontinued immediately*)

   - **b.** Development of renal disease

     (For example: *nPEP may also be stopped if you develop kidney disease or your kidneys show signs of distress, but you will need to speak with your doctor first and weigh the risks*.)

   - **c.** If identified person-source tests negative
     (For example: *If the source of the potential person source is negative, there is no need to continue taking nPEP, unless there other mitigating factors or potential source of exposure within 72 hours of when you started taking medication.*)

5. **Potential benefits/risks if pregnant or if pregnancy occurs during use of nPEP**
   - **a.** Effects on pregnant patients

     (For example: *If you're pregnant or plan on becoming pregnant while on nPEP, please discuss the risks and benefits of nPEP with your physician*.)

Checklist 2: Psycho-Social Wellness

1. **Assess how psycho-social factors may impact nPEP adherence**
   a. Ongoing abuse or trauma

   (For example: *Has recent or current sex partner ever hit, slapped, kicked, pushed or hurt you in any way? Could that impact your ability to take your medication twice a day?*)

   b. Homelessness or housing insecurity

   (For example: *Are you currently homeless, 'couch surfing, between permanent residence somewhere? Could that make it hard to stay on your medication for the whole 28 days?*)

   c. Substance use

(For example: *Do you share any injection works with other people? Do you have access to clean works or know how to wash your works? It's important for your safety and others to only used sterile syringes that are not used by other people. This is important to avoid spreading blood borne diseases like Hepatitis C and HIV.*

Do you drink more than 4-5 drinks in one sitting? How often? Has your drinking ever impacted your sexual decision making, or have you done something drunk you wouldn't do when you are sober?

Have you ever taken drugs that impacted your sexual decision making, or have you done something when you're using that you wouldn't do when you are sober?

It's important that while you're on nPEP you consistently practice safer sex, if you think you have may have a hard time doing this because of your drug or alcohol use, I can write you a referral for support or treatment.)

d. Mental Illness

(For example: Have you ever been told by a doctor or mental health professional that you have a mental health disorder? A lot of people have some type of mental health disorder, and work with mental health professionals to stay healthy through medication and other treatment. Certain mental illnesses can make it hard for you to take your medication twice a day. I can provide you with a referral if you aren't currently getting the mental health support you need to maintain your overall health.)

APPENDIX B: Resources for Insured Patients

Both Virginia Medicaid and Medicare formularies list nPEP medications, and are available to patients without HIV/AIDS at the discretion of a physician.

Co-pay costs will vary among insurance plans. There are several co-pay assistance programs available from the makers of each medication:

- **Gilead:** 1-877-505-6986 or http://www.gileadcopay.com/
- **Merck:** 1-855-834-3467 or https://www.activatethecard.com/7119/#
- **ViiV:** 1-877-784-4842 or www.viivhealthcareforyou.com

Additionally, the Patient Access Network Foundation (PAN) is a non-profit organization that provides assistance to under-insured patients for out-of-pocket expenses for HIV treatment and prevention, including PrEP or nPEP. **Patient insurance must cover the medications prescribed as a part of nPEP.** Apply online by at https://www.panapply.org/ or by calling 1-866-316- 7263