

**North Carolina Medical Board and North Carolina Board of Pharmacy Protocols for
Post Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)
July 16, 2025**

Pursuant to S.L. 2021-110, these protocols adopted by the North Carolina Medical Board and the North Carolina Board of Pharmacy authorize immunizing pharmacists practicing pharmacy in the state of North Carolina and licensed by the North Carolina Board of Pharmacy to dispense, deliver, or administer PEP therapy products as directed below.

HIV PEP Dispensing Protocol							
Exposure Timeline	<ul style="list-style-type: none">▪ Communicate with the patient to identify when the exposure took place▪ Assess the length of time since the exposure took place to determine if initiation of PEP is recommended or if the patient should be referred to a medical care provider as outlined in the Eligibility & Risk Screening section<ul style="list-style-type: none">- 72 hours or less: continue screening process- Greater than 72 hours: screening process should stop, but provide education on the lack of evidence on effectiveness of PEP initiation after 72 hours and refer patient to a medical care provider for HIV screening▪ Discuss with the patient the effectiveness of PEP based on time of initiation since exposure						
	<table><tr><th>Time Since Exposure (Hours)</th><th>CDC Guidelines Efficacy Evaluation</th></tr><tr><td>0-72</td><td>Effective</td></tr><tr><td>More than 72</td><td>No Evidence Supporting Efficacy</td></tr></table>	Time Since Exposure (Hours)	CDC Guidelines Efficacy Evaluation	0-72	Effective	More than 72	No Evidence Supporting Efficacy
	Time Since Exposure (Hours)	CDC Guidelines Efficacy Evaluation					
	0-72	Effective					
More than 72	No Evidence Supporting Efficacy						
Eligibility & Risk Screening	<p>For individuals age 13 years or older who voluntarily request Post-Exposure Prophylaxis and meet criteria for PEP initiation. Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025</p> <p>These protocols may be used for persons < 18 years of age with a parent or legal guardian consent.</p> <ul style="list-style-type: none">▪ The patient should be provided the Pharmacist-Initiated HIV Post-Exposure Prophylaxis Patient Questionnaire to screen the patient and to determine if an exposure occurred which would meet the criteria for PEP initiation<ul style="list-style-type: none">- High risk: PEP is recommended<ul style="list-style-type: none">▪ Intercourse (receptive or insertive) with a person known to be HIV positive▪ Needle sharing with a person known to be HIV positive▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person known to be HIV positive- Lower risk: recommendation of PEP should be evaluated on a case-by-case basis<ul style="list-style-type: none">▪ Intercourse (receptive or insertive) with a person with an unknown HIV status▪ Mouth to vagina, penis, or anus contact (insertive or receptive) with a person known to be HIV positive▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person with unknown HIV status▪ Exposed patient was consistently taking PrEP (pre-exposure prophylaxis)- For exposures determined to be lower risk, these additional risk factors should be assessed and the presence would weigh in favor of dispensing PEP therapy:<ul style="list-style-type: none">▪ Non-intact oral mucosa (i.e., cuts, sores)▪ The presence of blood▪ If either party had a genital ulcer▪ If either party had a sexually transmitted infection▪ If the other person had a detectable HIV viral load (>200 copies/mL)▪ Determination of HIV status<ul style="list-style-type: none">- Patient should be provided the Pharmacist-Initiated HIV Post-Exposure Prophylaxis Patient Questionnaire to self-report if they have ever tested positive for HIV- All persons considered for PEP who do not self-report they have tested positive in the past should have determination of their HIV infection status by HIV testing, preferably by using rapid combined Ag/Ab or antibody blood tests, including a rapid self-test.- If rapid HIV blood test results are unavailable, and PEP is otherwise indicated, it may be initiated without delay, but should be discontinued if the patient is later determined to have HIV infection▪ Sexual Assault<ul style="list-style-type: none">- If it is learned that the individual was a victim of sexual assault, refer the person to an emergency department or other medical facility specially trained to provide medical services for victims of sexual assault- In this instance, PEP may be initiated without delay, if there are no contraindications, with referral for specialty care						
Contraindications	<ul style="list-style-type: none">▪ Patient self-reports, or if a point-of-care HIV test is positive▪ > 72 hours since exposure▪ Known or suspected reduced renal function						
Precautions	<ul style="list-style-type: none">▪ Pregnancy (known or suspected) and breastfeeding▪ Follow the guidance given in the sections below for each of these considerations						

Safety Evaluation	<ul style="list-style-type: none"> Obtain a list of all current medications the individual seeking PEP therapy is taking, and perform a drug-drug interaction review https://www.hiv-druginteractions.org/checker. <ul style="list-style-type: none"> If there are no clinically-significant drug interactions between individual's current medications and PEP regimen: <ul style="list-style-type: none"> Proceed to dispense PEP therapy If there are clinically-significant drug interactions between current medications and PEP regimen: Step 1: Contact patient-authorized medical provider for guidance. If the authorized medical provider is not available: <ul style="list-style-type: none"> Step 2: Contact the National Clinician Consultation Center (NCCC) Post-Exposure Prophylaxis Hotline at (888) 448-4911 If further guidance on dispensing PEP for this individual based on drug interactions is unavailable via the authorized provider or the NCCC PEP Hotline; then Step 3: Refer the individual seeking PEP therapy to the Emergency Department or other medical provider If individual seeking PEP therapy is breastfeeding, follow Step 1-3 as outlined in this section. 	
Medication Dispensing	28-Day Regimen (See 'How Supplied' Below)	Alternative 28-Day Regimen (See 'How Supplied' Below)
	Individuals 13 years and older (Including Pregnant Patients)	
	<i>Bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg daily *</i> <i>*Available as a single tablet regimen</i>	Dolutegravir 50mg daily PLUS Tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine 200mg** OR tenofovir alafenamide (TAF) 25mg /emtricitabine 200mg** daily **Available as a combination tablet
How Supplied	Medications should be dispensed in accordance with manufacturer requirements. Some products require dispensing in unopened original containers, which may require the dispensing of a 30-day supply. A 30-day supply is allowed pursuant to these protocols.	
Refills	None. No limit on how many courses per patient per year (see Patient Education section for addressing risk mitigation).	
Patient Education Patient Education	<ul style="list-style-type: none"> Medication Education <ul style="list-style-type: none"> When 30-day supply is dispensed, emphasize the minimum treatment duration is 28 days. Drug information sheets that include side effects and adverse drug events for each medication dispensed should be given at the time medication is dispensed and patient should be counseled on what to do if they experience an adverse drug event. An offer to counsel should be made in accordance with standard North Carolina pharmacy practice Risk Mitigation <ul style="list-style-type: none"> Educational material on PEP should be provided Educational material on behaviors to avoid HIV exposure should be offered Pre-exposure Prophylaxis (PrEP) Education <ul style="list-style-type: none"> This should be considered when: <ul style="list-style-type: none"> An individual who reports behaviors or situation that place them at risk for frequently occurring HIV exposure (e.g. injection drug use, sex without condoms or other high-risk sexual behavior) More than 1 course of PEP therapy has been dispensed within a year If appropriate, written/verbal education on PrEP and the benefits of use should be provided HIV testing <ul style="list-style-type: none"> Each patient who receives PEP therapy shall be educated on the importance of having a test to determine their HIV infection status. Pharmacist shall educate the patient on self-test HIV kits and local HIV testing site options. Pharmacist shall educate the patient that if their HIV test is positive, they should discontinue taking PEP and seek care from a medical provider for treatment. Emphasize the importance of receiving follow-up care from a medical provider to ensure: <ul style="list-style-type: none"> Assessment for signs and symptoms of acute HIV infection Full evaluation of the exposure Receipt of HIV testing four to six weeks and three months after exposure, or anytime if the patient develops symptoms of acute HIV infection Information on resources available for HIV exposure Inform the patient of the importance of completing the full 28-day course of PEP therapy unless directed otherwise by a medical provider Patients who report intravenous drug use should be assessed for their interest in substance use disorder treatment and information on services should be made available for those who desire treatment. Information on safer syringe use should be shared with those who continue to inject or who are at risk for relapse. 	

Notification	Pharmacists choosing to dispense PEP, under the authority of these protocols, shall notify the patient's primary care provider within 72 hours of providing therapy. Notification should include the pharmacist's name and NPI #, and the pharmacy/practice name and phone number, exposure history and medicines dispensed. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary care provider, and provide information regarding primary care providers, including private practices, federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.
Medication access	<ul style="list-style-type: none"> • The generic formulation of emtricitabine/TDF is generally covered as a tier 1 medication on most commercial health plans. • Patients who are commercially insured may be eligible for copay savings cards for branded medications through the drug manufacturer. Information can be found on each of the manufacturer's websites. • As of November 1, 2023, NC Medicaid covers all HIV antiretroviral medications with copayments waived • Uninsured clients may qualify for assistance with Bictegravir/TAF/emtricitabine (Biktarvy®) or emtricitabine/TAF (Descovy®) through Gilead Advancing Access 1-800-226-2056 and for Dolutegravir (Tivicay®) through ViiV Connect 1-800-226-2056.

Pharmacist-Initiated HIV Post-Exposure Prophylaxis

Patient Questionnaire

Part I: Patient Information

Patient Name _____ Birth Date: _____ Age: _____ Visit Date: _____
First Last MM/DD/YY MM/DD/YY
Address: _____ City: _____ State: _____ Zip Code: _____
Phone: (____) _____ Primary Care Provider: _____

Part II: Patient History

Allergies: _____

Please list all of your current medications, including nonprescription medications and dietary supplements:

Have you ever tested positive for HIV?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	If yes, when? _____ <i>Date</i>
Are you currently pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
Are you able to become pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
Have you ever been diagnosed with kidney disease or told by a medical provider that you have decreased kidney function?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
Have you ever taken PEP in the past?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	If yes, when? _____ <i>Date</i>
If you answered yes to the previous question, did you have any side effects or serious problems?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	If yes, please explain: _____ _____ _____

In the last 3 days (72 hours) have you experienced any of the following:

High-Risk <ul style="list-style-type: none">• Intercourse (receptive or insertive) with a person known to be HIV positive• Needle sharing with a person known to be HIV positive• Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person known to be HIV positive	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Lower-Risk <ul style="list-style-type: none">• Intercourse (receptive or insertive) with a person with an unknown HIV status• Mouth to vagina, penis, or anus contact (insertive or receptive) with a person known to be HIV positive• Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person with unknown HIV status	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Estimated time of potential exposure (XX:XX AM/PM, MM/DD/YY): _____

Estimated hours elapsed since exposure: _____

**Pharmacist-Initiated HIV Post-Exposure Prophylaxis
Documentation & Communication Form**

Part I: Patient Information

Patient Name _____ Birth Date: _____ Age: _____ Visit Date: _____
First Last MM/DD/YY MM/DD/YY
Address: _____ City: _____ State: _____ Zip Code: _____
Phone: (____) _____ Primary Care Provider: _____

Part II: PEP Dispensing

At the time of dispensing did the patient have an HIV test performed? <i>If yes, results were</i> <i>If no, was information provided on self-testing and local testing site options?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> Positive <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Negative <input type="checkbox"/> No
Was a Drug-Drug Interaction Screening Performed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Not Applicable
Drug Therapy Dispensed: _____	Day-Supply Dispensed: _____	

Part II: Education

Education Provided: ☐ Medication education for PEP regimen ☐ Risk mitigation
☐ Necessity for PCP or health dept follow-up ☐ Importance of HIV testing

Part III: Patient Consent to Release of Information

By signing this document, I agree to:

- Seek HIV testing, if not already done
- Seek follow-up care with my primary provider, local health department or clinic; and
- Allow the pharmacist/pharmacy to release information about my care today to my primary provider or the medical provider of my choosing.

Signature: _____ **Date:** _____
PATIENT SIGNATURE

Pharmacist Name _____
Date

Pharmacist NPI# *Pharmacy Name* _____
Pharmacy Phone #

Faxed to Primary Care Provider on _____ by _____
Date Responsible Party

For Pharmacy Use Only

An attempt was made to follow-up with the patient to inquire as to whether the patient did schedule/keep an appointment for HIV testing and follow-up care with primary care or other medical provider.

Date Follow-up Attempted *Method of Contact* Patient Reached ☐ Yes ☐ No
Notes: _____