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BUILDING CAPACITY TO IMPROVE HEALTH

nPEP Toolkit
to Prevent HIV Infection

Maryland
DEPARTMENT OF HEALTH

HealthHIV

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Introduction

This toolkit contains key elements regarding Non-Occupational Post-Exposure Prophylaxis (nPEP) management. Frequent changes in standards of HIV prevention and care require that the guidelines be carefully reviewed by the medical team in your facility to assure that they conform to acceptable local and current approaches. Medical prevention and treatment updates are posted frequently to several websites, including the websites at https://hivinfo.nih.gov/home-page and https://www.cdc.gov.

It is recommended that every provider be familiar with all relevant guidelines.

This document is not intended to replace clinical research literature or current United States Public Health Service (USPHS) Guidelines, and may not include the full range of prevention and treatment options for all patients. If there are questions regarding the provision of nPEP, it is recommended that a provider contact the **Clinician Consultation Center PEPLINE at 1-888-448-4911**.

This toolkit aims to achieve the following goals:

- Reinforce that HIV exposure is an emergency that requires rapid response, with immediate administration of the first dose of PEP medications.
- Reduce under- and over-prescribing of PEP by describing the benefits of PEP and providing guidance for identifying high-risk HIV exposures for which PEP is indicated.
- Ensure prescription of PEP regimens that are effective and well tolerated.
- Assist clinicians in recognizing and addressing challenges to successful completion of a PEP regimen.
- Detail the baseline testing, monitoring, and follow-up that should accompany prescription of a 28-day course of PEP.

Situations That May Require a Risk Assessment for nPEP

Unprotected vaginal or anal sex with known (or likely) HIV positive partner

Unprotected receptive anal, vaginal, and oral sex are amongst the highest tranmissible forms of sexual activites. While all exposure types are not equal in the transmission process, some types carry higher risk of HIV transmission than others.

RECEPTIVE AND INSERTIVE ANAL (UNPROTECTED)

- Receptive and Insertive: 39.9%
- HIV-negative partner who engages solely in insertive: 21.7%,
- HIV-negative receptive partner: 40.4%.
  [Patel et al., 2014]

VAGINAL (UNPROTECTED)

Risk factors in women:

- The risk of transmitted disease from vaginal sex without condom use is higher among women. (1 in 1250 will contract HIV)
- Insertive vaginal sex (1 in 2500 will contract HIV)
  [CDC, n.d.]

ORAL (UNPROTECTED)

- There is little to no risk of getting or transmitting HIV from oral sex.
- Other STDs and hepatitis can be transmitted during oral sex.
- The risk of HIV from oral sex can run anywhere from 0%–1% *[CDC, 2016]*
- More than 85% of sexually active adults aged 18-44 years reported having oral sex at least once with a partner of the opposite sex
- 2011 to 2015 found that 41% of teenagers aged 15-19 years reported having oral sex with a partner of the opposite sex
  [CDC, n.d.]

Injection drug use needle exposure

Adult and adolescent PWID accounted for 10% (3,864) of the 37,968 new HIV diagnoses in the United States (US) in 2018 (2,492 cases were attributed to injection drug use and 1,372 to male-to-male sexual contact and injection drug use). *[CDC, June 28, 2022]*

MARYLAND

- In 2020, there were 45 reported HIV diagnoses among persons with IDU exposure.
- Of the 724 reported HIV diagnoses in 2020, 6.2% were attributed to IDU and 0.9% were among MSM/IDU.
- Of the 531 male and 193 total female HIV diagnoses, 5.1% and 9.1%, respectively were attributed to IDU exposure.
- It is estimated that an additional 2.9% of persons with IDU exposure living with HIV in Maryland remain undiagnosed, as of 2019.
- Of the 31,676 people living with diagnosed HIV in 2020, 15.9% were attributed to IDU exposure. Among males, 13.8% were attributed to IDU exposure and 5.4% to MSM/IDU. Among females, 20.0% were attributed to IDU exposure.
- IDU exposure was highest among individuals 60 and older (43.2%) and among NH-Black people (80.7%).
- Of the people living with diagnosed HIV attributed to IDU exposure, 72.9% had a viral load test result reported in 2020. Of those with a reported viral load test, 89.5% had a suppressed viral load.
  [Maryland.gov, 2020]

Contact with blood

- Contact with blood via non-intact skin (open cut or wound) or mucus membrane (eyes, nose, mouth, etc.) is very low risk.

Sexual assault

The prevalence of HIV transmission during sexual assault is unknown, but it is expected that it is greater in nonconsensual intercourse, or sexual assault, due to potential injuries sustained by the victim. This is especially true for child victims who may suffer repeated abuse and more severe injuries. These factors may increase the risk of HIV transmission from a sexual assault when the offender(s) is/are HIV positive (CDC, 2005):

- Bite injuries
- Multiple offenders
- Vaginal and anal penetration
- Genital trauma and/or vaginal or anal tears
- The presence of sperm or semen in/around the vagina or anus
- Offender(s) that are injection drug user(s)

Sexual Assault Exposure Risk in the United States

Statistics on sexual assault in the United States show high rates of attempted or completed rape among several populations, including cisgender women, men, children, and transgender individuals:

21.3% of women reported rape or attempted rape in their lifetime. Of those, **43.2%** were first assaulted before age 18. [Smith SG, et al. 2018]

1.4% of men reported rape or attempted rape in their lifetime, with their first experience occurring before age 18 years in **26%** (~2 million). [Smith SG, et al. 2018]

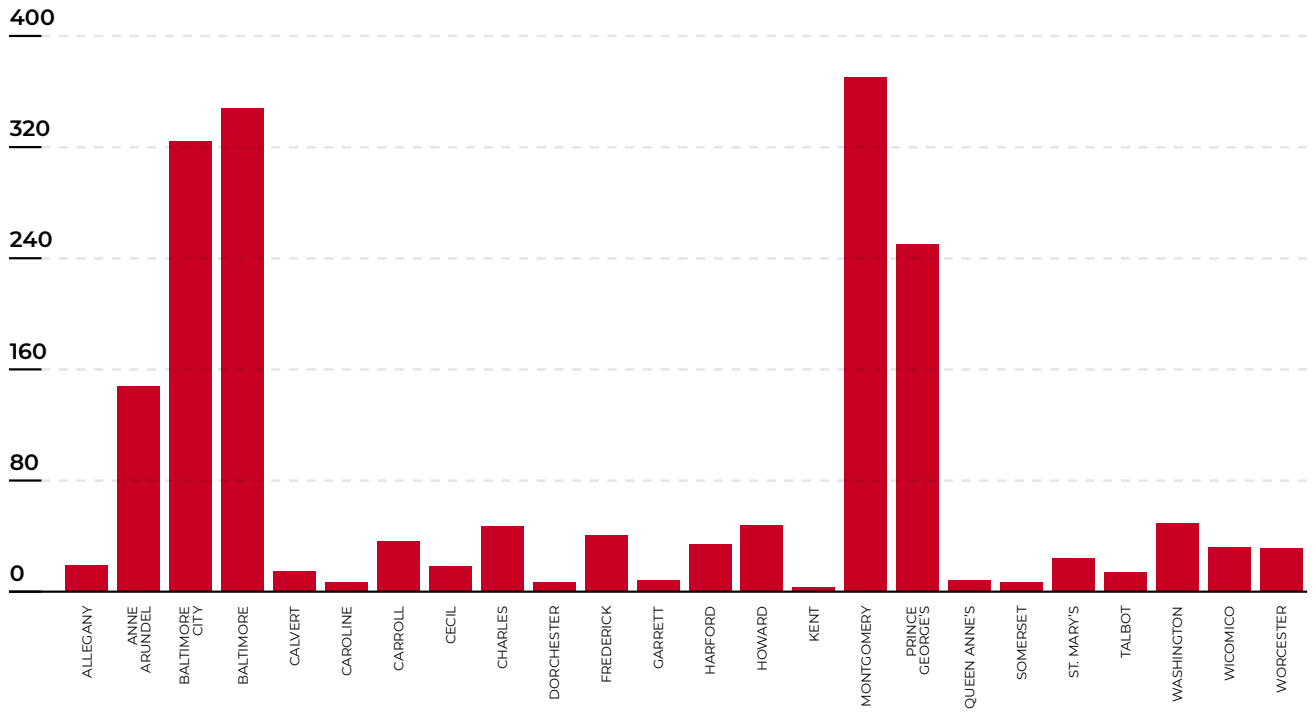
26% of women and **15%** of men who were victims of sexual violence, physical violence, or stalking by an intimate partner first experienced these or other forms of violence **before age 18 years**. [CDC 2019]

47% of respondents to the 2015 U.S. Transgender Survey reported that they had been sexually assaulted in their lifetime; **10%** reported that they had been assaulted in that past year. [James, et al. 2016]

Sexual Assault and Rape in Maryland

A total of 1,891 reported rapes were reported in 2020 and 1,979 in 2019. The three Maryland counties with the most rape reports were Baltimore County, Baltimore City, and Montgomery County.

REPORTED RAPES IN MARYLAND BY COUNTY, 2020



Maryland women have a high lifetime prevalence of sexual violence other than rape, totaling an estimated number of 1,773,000 women.

An estimated 441,000 Maryland men have **experienced sexual violence other than rape in their lifetime**.

Approximately 391,000 Maryland women have experienced **contact sexual violence by an intimate partner** in their lifetime.

An estimated 420,000 Maryland women have experienced rape, or **18.2%** of the female population. However, an estimated **22.3% of non-Hispanic black women** in Maryland have experienced rape, compared to **18%** of white women.

An estimated 329,000 Maryland men have experienced **contact sexual violence** in their lifetime, or 15.6% of the male population in the state.

Sexual assaults and rapes are still some of the most underreported crimes, and yearly trends suggest a steady decrease in reporting. This may be due to several barriers, including fear of retaliation, perception of insufficient evidence, fear of the criminal justice system, or belief that the police could not, or would not, help. [Maryland State Police, 2021]

Risk of HIV infection

Increased risk of infection in cases of sexual assault has been associated with trauma at the site of exposure and absence of barrier protection. PEP is the only proven method of reducing HIV acquisition after exposure, and it should be offered in cases of sexual assault. There are published reports of HIV seroconversion following sexual assault [Myles, *et al.* 2000; Albert, *et al.* 1994; Claydon, *et al.* 1991; Murphy, *et al.* 1989].

PEP (post-exposure prophylaxis) is effective in preventing HIV infection when it is administered rapidly—ideally within two hours and not later than 72 hours—after a high-risk exposure.

Post-Exposure Prophylaxis Checklist for Providers

Before Starting

- The patient is at risk of contracting HIV (see "Risk Assessment" sheet).
- It has been 72 hours or less since exposure.
- The patient is capable of adhering to a daily two pill regimen and returning to the office for refills and lab work in 4 weeks and 12 weeks.
- Perform both an HIV test and an HIV qualitative RNA/Nucleic Acid Amplification Test (NAAT).
- The patient does not have known renal impairment (eGFR of < 60 mL/min, Cockcraft Gault).
- The patient received counseling and was informed that PEP does not protect against other Sexually Transmitted Infections; thus, risk-reduction strategies, such as avoiding intercourse with partners of unknown STI status and the usage of condoms remains necessary.
- Discuss paying for PEP (see "Payment Assistance") and consider completing Advancing Access or Co-Pay Assistance Coupon forms. If the patient will have difficulty paying for labs or office visits, consider referring the patient to a community health center or federally qualified health center (FQHC) with an established PEP program.
- Maryland minor consent law — "A minor (i.e., a person under the age of 18) has the same capacity as an adult to consent to treatment for or advice about venereal disease [Md. Code Ann., Health-Gen. II § 20-102(c)(1)-(5)]"

Lab Tests

- HIV: fourth generation dual antibody/antigen test is preferred. A third generation test or finger-stick Point of Care test is acceptable, but oral swab rapid tests are not approved for HIV testing in the context of PrEP. Consider adding a qualitative HIV NAAT to the HIV test if suspected acute infection.
- Three-site STI screening:
  - Oropharyngeal and urine neisseria gonorrhea(Gc)/chlamydia trachomatis (Ct) NAAT for all patients
  - Self-administered rectal swab Gc/Ct NAAT for patients who participate in receptive anal sex
  - Syphilis screening
- Hepatitis B surface antigen (HBsAg); consider a full hepatitis panel; vaccination recommended for those non-immune to hepatitis B or hepatitis A, especially MSM.
- Serum Creatinine or Basic Metabolic Panel (preferred) for all patients; consider a comprehensive metabolic panel for patients taking hepatically metabolized medications, who have a history of alcoholism, or who have other conditions concerning underlying liver disease.
- Baseline urinalysis for all patients to screen for proteinuria.
- Pregnancy test for people of child bearing age. Truvada is a Pregnancy B medication; it is often used in pregnant persons living with HIV. There is limited data on the safety of Truvada during breastfeeding. Discuss the risks and benefits of Truvada with the patient if they are pregnant.

Counseling Patients on PEP

- Emphasize the importance of adherence to all medication regimens.
- Discuss possible side effects (headache, nausea, vomiting, diarrhea, fatigue).

Prescribing PEP

- Prescribe Truvada and Isentress (or Tivicay) once daily PO, disp #30 tablets, without refills. Do not wait for lab results.
- Schedule patient's first follow-up visit in 28 days for further testing and to discuss adherence and side-effects.

Follow-Up Visits (At 28 days, then 90 days)

Lab Tests

- Weeks 4 and 12: 4th generation dual antibody/antigen HIV test (preferred) or 3rd generation test. Consider a qualitative HIV NAAT if suspected acute infection.
- Week 4: Pregnancy test for persons of child-bearing capacity.
- Week 2 and 4: SCr or Basic or Comprehensive Metabolic Panel (only if baseline was abnormal).
- Week 12: Hepatitis B,C screening if indicated.

Four Action Steps of nPEP

Step One: Evaluation

Evaluation of the patient exposed to HIV should be conducted with the highest level of confidentiality. HIV reporting should take place as required by Maryland state law.

Circumstances of the Exposure and nPEP Management

The following circumstances of the exposure and nPEP management* should be recorded in the medical record with details, including:

- **Exposure:** Date and time of exposure (is it within 72 hours?)
- **Exposure Type:** Details of the exposure, including, type and amount of fluid or material and severity of exposure
- **Incident:** Details of the incident: where and how exposure occurred, exposure sites on body
- **Source:** Details about exposure source, if available:
  - HIV, hepatitis B and hepatitis C status
  - If the source is living with HIV, determine the stage of disease, HIV viral load, current and previous antiretroviral therapy and antiretroviral resistance information
- **Patient:** Details about the patient exposed to HIV:
  - Hepatitis A and hepatitis B vaccination and vaccine-response status
  - Other medical conditions, drug allergies and medications
  - Pregnancy and breast-feeding status

* *nPEP is not indicated for perceived exposures of negligible or no conceivable risk. Clinicians should be willing to decline requests for nPEP and provide supportive counseling and referrals in these situations.*

Exposures that do not warrant nPEP	Lower Risk Exposures	Higher Risk Exposures
▶ Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation) ▶ Human bites not involving blood ▶ Exposure to solid-bore needles or sharps not in recent contact with blood ▶ Mutual masturbation without skin breakdown or blood exposure	▶ Receptive and Insertive: ■ Oral-vaginal contact ■ Oral-anal contact ▶ Receptive penile-oral contact with or without ejaculation ▶ Insertive penile-oral contact with or without ejaculation	▶ Receptive and insertive vaginal or anal intercourse with PLHIV or person with unknown HIV status ▶ Needle sharing with PLHIV or person with unknown HIV status ▶ Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needle sticks with a hollow-bore needle, human bites, accidents)
STOP **nPEP not indicated. Provide risk-reduction counseling and offer HIV test.**	**STOP** **nPEP not indicated. Provide risk reduction counseling and offer HIV test.**	**If nPEP is indicated, evaluate time since exposure.**

Is patient presenting within 72 hours?
CDC guidance is to initiate nPEP if a patient presents within 72 hours of exposure. See MMWR CDC nPEP Guidelines 2016: https://www.cdc.gov/mmwr/volumes/65/wr/mm6517a5.htm

Step Two: Risk Assessment

The exposure should be evaluated for the potential to transmit HIV based on (1) the type of body substance involved, (2) the route and (3) HIV status of the source.

- Decisions should be individualized, weighing the likelihood of transmission against the potential benefits and risks of treatment, and adherence to the course of PEP medications.
- If the patient is too distraught to engage in a discussion about and/or commitment to the drug regimen at the initial assessment, the clinician should offer a first dose of the medication and make arrangements for a follow up within 24 hours to further discuss the indications for nPEP.

HIV Status Assessment

The likelihood of pre-existing HIV infection should be determined for all individuals presenting for nPEP. The following information should be obtained:

- Has the patient ever been tested, and if so, what was the date/result of their last HIV test?
- The number and types of unprotected exposures since the last HIV test.
- The likelihood of pre-existing HIV infection should be reviewed with the patient prior to nPEP prescription. If pre-existing HIV infection is likely, this information should be integrated into the risk-benefit assessment.

People Who Have Experienced Sexual Assault

All exposures sustained during sexual assault should be considered a risk for HIV. nPEP should be considered in all cases of sexual assault, especially in cases where the assailant is unknown. It is reasonable to offer nPEP to patients who have been sexually assaulted by persons who are known to them, but whose sexual and injection drug use history is not known. Multiple other factors can be considered to determine the likelihood that the exposure source is living with HIV.

- The National Sexual Assault Hotline, 1-800-656-HOPE (4673) offers Rape Crisis Center services to mitigate sexual assault trauma.
- Maryland Coalition Against Sexual Assault (MCASA), https://www.mcasa.org or https://mcasa.org/survivors/find-a-rape-crisis-center

RECOMMENDED REGIMEN FOR ADOLESCENT AND ADULT FEMALE SEXUAL ASSAULT SURVIVORS

- For Gc: Ceftriaxone 500 mg* IM in a single dose plus
- For Ct: Doxycycline 100 mg 2 times/day orally for 7 days plus
- For trichomonas: Metronidazole 500 mg 2 times/day orally for 7 days

* For persons weighing ≥150 kg, 1 g of ceftriaxone should be administered.

RECOMMENDED REGIMEN FOR ADOLESCENT AND ADULT MALE SEXUAL ASSAULT SURVIVORS

- Ceftriaxone 500 mg* IM in a single dose plus
- Doxycycline 100 mg 2 times/day orally for 7 days

* For persons weighing ≥150 kg, 1 g of ceftriaxone should be administered.

Baseline Testing

- HIV Ag/Ab: Rapid (point of care) 4th generation (Ag/Ab) test is preferred, but if not available, a rapid Ab test or a non-rapid lab-based HIV test should be done. If non-rapid testing is done, start nPEP immediately and arrange follow-up in 1-2 days for HIV results.
- Serum liver enzymes, blood urea nitrogen, creatinine.
- Complete blood count.
- Pregnancy (individuals of childbearing capacity).
- Hepatitis B serology panel (surface antigen, surface antibody).
- CV antibody.
- Rapid plasma reagin (RPR).
- Gonorrhea/chlamydia nucleic acid amplification test (NAAT), by site.
- Trichomonas NAAT.

Treatment of the patient is the PRIORITY and should NOT be delayed while waiting for lab results.

To review the CDC HIV Risk Reduction Tool, visit https://hivrisk.cdc.gov/risk-estimator-tool/#-sb.

Step Three: Treatment

A 28-day course of nPEP is recommended for persons who are not living with HIV who seek care ≤ 72 hours after a nonoccupational exposure to blood, genital secretions, or other potentially infectious body fluids of persons known to be living with HIV or of unknown HIV status when that exposure represents a substantial risk for HIV acquisition. Since adherence is critical for nPEP efficacy, it is preferable to select regimens that minimize side effects, number of doses per day and the number of pills per dose.

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	**Preferred**	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada) once daily ***with*** raltegravir (Isentress) 400 mg twice daily ***or*** dolutegravir (Tivicay) 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada) once daily ***with*** darunavir (Prezista) 800 mg (as 2,400-mg tablets) once daily ***and*** ritonavir (Norvir) 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A 3-drug regimen consisting of zidovudine (Retrovir) ***and*** lamivudine (Epivir), with both doses adjusted to degree of renal function ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** darunavir 800 mg (as 2,400-mg tablets) once daily ***and*** ritonavir 100 mg once daily
Children aged 2–12 years	**Preferred**	A 3-drug regimen consisting of tenofovir DF, emtricitabine, and raltegravir, with each drug dosed to age and weight
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine ***with*** raltegravir ***or*** lopinavir/ritonavir (Kaletra), with raltegravir and lopinavir/ritonavir dosed to age and weight
	Alternative	A 3-drug regimen consisting of tenofovir DF ***and*** emtricitabine ***and*** lopinavir/ritonavir, with each drug dosed to age and weight
Children aged 3–12 years	Alternative	A 3-drug regimen consisting of tenofovir DF ***and*** emtricitabine ***and*** darunavir/ritonavir, with each drug dosed to age and weight
Children aged 4 weeks–< 2 years	**Preferred**	A 3-drug regimen consisting of zidovudine oral solution ***and*** lamivudine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir oral solution, with each drug dosed to age and weight
	Alternative	A 3-drug regimen consisting of zidovudine oral solution ***and*** emtricitabine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir oral solution, with each drug adjusted to age and weight
Children aged birth–27 days	Consult a pediatric HIV-specialist	

Abbreviations: HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.

Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active against HIV in the above "3- drug" regimens.

Darunavir only FDA-approved for use among children aged ≥ 3 years.

Children should have attained a postnatal age of ≥ 28 days and a postmenstrual age (i.e., first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks.

Formulations, cautions, and dose adjustments for antiretroviral medications in preferred and alternative nPEP regimens

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Tenofovir disoproxil fumarate (TDF) (Viread, Gilead Sciences, Inc., Foster City, California) Also available as component of fixed-dose combination, Truvada (Gilead Sciences, Inc., Foster City, California) (emtricitabine + TDF)	▸ 150-mg tablet ▸ 200-mg tablet ▸ 250-mg tablet ▸ 300-mg tablet ▸ 40-mg/gm powder	**Side effects:** Asthenia, headache, diarrhea, nausea, vomiting **Contraindications:** Nephrotoxicity; for nPEP, should not be administered to persons with acute or chronic kidney injury or those with eCrCl < 60 mL/min **Cautions:** TDF can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug may cause an acute hepatitis exacerbation.	**Children aged 2–11 years (powder)** ▸ 8 mg/kg body weight ▸ Not to exceed adult dose (300 mg qd) **Children aged 2–11 years (tablet), per body weight** ▸ 17 to < 22 kg, 150 mg-tablet once daily ▸ 22 to < 28 kg, 200 mg-tablet once daily ▸ 28 to < 35 kg, 250-mg tablet once daily ▸ ≥35 kg, 300-mg tablet once daily ▸ Not to exceed adult dose (300 mg once daily)
Emtricitabine (FTC) (Emtriva, Gilead Sciences, Inc., Foster City, California) Also available as component of fixed-dose combination, Truvada (FTC + TDF)	▸ 200-mg capsule ▸ 10-mg/mL oral solution	**Side effects:** Hyperpigmented rash or skin discoloration **Cautions:** FTC can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug might cause an acute hepatitis exacerbation. **Contraindications**: Do not administer with lamivudine	**Children aged 0–3 months (oral solution)** ▸ 3 mg/kg once daily ▸ Not to exceed 240 mg once daily **Children aged 3 months–17 years, per body weight** ▸ 6 mg/kg once daily (oral solution) ▸ ≥33 kg 200-mg tablet once daily ▸ Not to exceed 240 mg once daily
Raltegravir (RAL) (Isentress, Merck & Co., Inc., Kenilworth, New Jersey)	▸ 400-mg tablet ▸ 100-mg chewable, scored tablet ▸ 25-mg chewable tablet	**Side effects:** Insomnia, nausea, fatigue, headache; severe skin and hypersensitivity reactions have been reported **Cautions:** Dosage adjustment required if co-administered with rifampin (800 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and certain oral multivitamins can reduce absorption of RAL. RAL should be administered ≥ 2 hours before or ≥ 6 hours after administration of cation-containing medications or products, however, RAL can be co-administered with calcium carbonate containing antacids. **Contraindications:** None	**Children aged 6–12 years and weighing > 25 kg** ▸ 400 mg-tablet twice daily **Or** ▸ Chewable tablets twice daily. See table below for chewable tablet dose. **Children aged 2–12 years (chewable tablets), per body weight** ▸ 11 to < 14 kg, 75-mg twice daily ▸ 14 to < 20 kg, 100-mg twice daily ▸ 20 to < 28 kg, 150-mg twice daily ▸ 28 to < 40 kg, 200-mg twice daily ▸ ≥ 40 kg, 300-mg twice daily

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Dolutegravir (DTG) (Tivicay, ViiV Healthcare, Brentford, Middlesex, United Kingdom)	▸ 50-mg tablet	**Side effects:** Insomnia, headache **Cautions:** Dosage adjustment required if co-administered with rifampin, fosmamprenavir/ritonavir, tipranvir/ritonavir, or efavirenz (50 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and some oral multivitamins can reduce absorption of DTG. DTG should be administered ≥2 hours before or at ≥6 hours after administration of cation containing medications or products. **Contraindications:** Do not administer with dofetilide.	**Children aged 12 years old and older and weighing ≥40 kg** ▸ 50-mg tablet once daily
Darunavir (DRV)/ ritonavir (RTV) (Prezista, Janssen Therapeutics, Titusville, New Jersey)	▸ 75-mg tablet ▸ 150-mg tablet ▸ 400-mg tablet ▸ 600-mg tablet ▸ 100-mg/mL oral suspension	**Side effects:** Rash (sulfonamide allergy), diarrhea, nausea, headache **Cautions:** Must be administered with food; must be co administered with ritonavir; can cause hepatotoxicity. Use with caution with persons with known allergy to sulfonamide medications **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life threatening adverse events.	**Children aged 3 to < 18 years and weight > 10 kg WEIGHT (KG) DOSE (TWICE DAILY WITH FOOD)** ▸ 10 to < 11 kg* darunavir 200 mg (2.0 mL) plus ritonavir 32 mg (0.4 mL†) ▸ 11 to < 12 kg* darunavir 220 mg (2.2 mL) plus ritonavir 32 mg (0.4 mL†) ▸ 12 to < 13 kg* darunavir 240 mg (2.4 mL) plus ritonavir 40 mg (0.5 mL†) ▸ 13 to < 14 kg* darunavir 260 mg (2.6 mL) plus ritonavir 40 mg (0.5 mL†) ▸ 14 to < 15 kg* darunavir 280 mg (2.8 mL) plus ritonavir 48 mg (0.6 mL†) ▸ 15 to < 30 kg darunavir 375 mg (combination of tablets or 3.8 mL‡) plus ritonavir 48 mg (0.6 mL†) ▸ 30 to < 40 kg darunavir 450 mg (combination of tablets or 4.6 mL‡) plus ritonavir 100 mg (tablet or 1.25 mL†) ▸ ≥ 40 kg darunavir 600 mg (tablet or 6 mL) plus ritonavir 100 mg (tablet or 1.25 mL†) * The dose in children weighing 10–15 kg is 20 mg/kg darunavir and 3 mg/kg ritonavir per kg body weight per dose, which is higher than the weight-adjusted dose in children with higher weight. † Ritonavir 80 g/mL oral solution ‡ The 375-mg and 450-mg darunavir doses are rounded for suspension-dose convenience.

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Lopinavir (LPV)/ ritonavir (RTV) (Kaletra, AbbVie Inc., North Chicago, Illinois)	▸ 200/50-mg tablets ▸ 100/25-mg tablets ▸ 80/20-mg/mL oral solution	**Side effects:** Nausea, vomiting, diarrhea **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Do not administer to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥42 weeks and a postnatal age of ≥14 days. **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life threatening adverse events.	**Children aged 14 days–12 months, per body weight** *Suspension (lopinavir/ritonavir)* ▸ 16/4 mg/kg or 300/75 mg/m2 twice daily **Children aged > 12 months–18 years, per body weight** *Suspension (lopinavir/ritonavir)* ▸ < 15 kg, 12/3 mg/kg twice daily ▸ ≥15 kg to 40 kg, 10/2.5 mg/kg twice daily ▸ > 40 kg, 400/100 mg twice daily ▸ not to exceed the recommended adult dose (400/100 mg [5 mL] twice daily **Children aged > 12 months–18 years** *Tablet, weight-based dosing (lopinavir/ ritonavir)* ▸ 15 to 25 kg, 2 100/25-mg tablets twice daily ▸ > 25 to 35 kg, 3 100/25-mg tablets twice daily ▸ > 35 kg, 4 100/25-mg tablets twice daily or 2 200/50-mg tablets twice daily
Lopinavir (LPV)/ ritonavir (RTV) (Kaletra, AbbVie Inc., North Chicago, Illinois)	▸ 200/50-mg tablets ▸ 100/25-mg tablets ▸ 80/20-mg/mL oral solution	**Side effects:** Nausea, vomiting, diarrhea **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Do not administer to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥42 weeks and a postnatal age of ≥14 days. **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life threatening adverse events.	**Children aged 14 days–12 months, per body weight** *Suspension (lopinavir/ritonavir)* ▸ 16/4 mg/kg or 300/75 mg/m2 twice daily **Children aged > 12 months–18 years, per body weight** *Suspension (lopinavir/ritonavir)* ▸ < 15 kg, 12/3 mg/kg twice daily ▸ ≥15 kg to 40 kg, 10/2.5 mg/kg twice daily ▸ > 40 kg, 400/100 mg twice daily ▸ not to exceed the recommended adult dose (400/100 mg [5 mL] twice daily **Children aged > 12 months–18 years** *Tablet, weight-based dosing (lopinavir/ ritonavir)* ▸ 15 to 25 kg, 2 100/25-mg tablets twice daily ▸ > 25 to 35 kg, 3 100/25-mg tablets twice daily ▸ > 35 kg, 4 100/25-mg tablets twice daily or 2 200/50-mg tablets twice daily

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Ritonavir (RTV) (Norvir, AbbVie, Inc., North Chicago, Illinois)	▸ 100-mg tablets ▸ 100-mg soft gelatin capsules ▸ 80-mg/mL oral solution	**Side effects:** Abdominal pain, asthenia, headache, malaise, anorexia, diarrhea, dyspepsia, nausea, vomiting, circumoral paresthesia, peripheral paresthesia, dizziness, and taste perversion. **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Can cause hepatotoxicity, pancreatitis, or hyperglycemia **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life threatening adverse events.	▸ See pediatric dosage for use as a boosting agent with darunavir or lopinavir in respective darunavir and lopinavir sections of this table.
Zidovudine (ZDV; AZT) (Retrovir, ViiV Healthcare, Brentford, Middlesex, United Kingdom)	▸ 100-mg capsule ▸ 300-mg tablet ▸ 10-mg/mL oral syrup 10-mg/mL intravenous infusion	**Side effects:** Nausea, vomiting, headache, insomnia, and fatigue **Cautions:** Can cause anemia and neutropenia	**Infants aged birth–41 days** **Full term (aged ≥35 weeks gestation at birth), per body weight** *Syrup* ▸ 4 mg/kg orally twice daily *Intravenous* ▸ 3.0 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged ≥30 to 35 weeks gestation at birth; from birth through day 14 of life; switch to full term infant dose at 15 days of life), per body weight** *Syrup* ▸ 2 mg/kg orally twice daily *Intravenous* ▸ 1.5 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged < 30 weeks gestation at birth; day 14–28 of life; switch to full term infant dose at 29 days* of life), per body weight** *Syrup* ▸ 2 mg/kg orally twice daily *Intravenous* ▸ 1.5 mg/kg, infused over 30 minutes, every 12 hours **Infants and children aged ≥35 weeks post-conception and at least 4 weeks post-delivery, per body weight** *Syrup or Capsules* ▸ 4 to < 9 kg, 12 mg/kg twice daily ▸ 9 to < 30 kg, 9 mg/kg twice daily *Tablet* ▸ ≥30 kg, 300-mg tablet twice daily * Note: Premature infants exposed to HIV after day 1 of life are switched to full-term infant dose at 29 days of life.

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Lamivudine (3TC) (Epivir, ViiV Healthcare, Brentford Middlesex, United Kingdom)	▸ 150-mg scored tablet ▸ 100-mg tablet ▸ 300-mg tablet ▸ 10-mg/mL oral solution	**Side effects:** Headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough **Cautions:** 3TC may be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped since withdrawal of this drug may cause an acute hepatitis exacerbation. **Contraindications:** Do not administer with emtricitabine	**Neonates and infants, aged ≤27 days** *Oral solution* ▸ 2 mg/kg twice daily **Children, aged ≥4 weeks** *Oral solution* ▸ 4 mg/kg (maximum dose 150 mg) twice daily **Children aged < 16 years and weighing ≥14 kg** *Scored 150-mg tablet* ▸ 14 to < 20 kg, 75 mg (1/2 tablet) AM + 75 mg (1/2 tablet) PM ▸ 20 to < 25 kg, 75 mg (1/2 tablet) AM + 150 mg (1 tablet) PM ▸ ≥25 kg, 150 mg tablet twice daily **Adolescents (aged ≥16 years) and adults, per body weight** ▸ < 50 kg, 4 mg/kg (up to 150 mg) twice daily ▸ ≥50 kg, 150 mg twice daily or 300 mg once daily

Abbreviations: 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); nPEP, nonoccupational postexposure prophylaxis.

For most current dosing regimens for treatment naïve children, see

1) AIDSInfo Drugs Database at https://clinicalinfo.hiv.gov/en/drugs

2) Drugs@FDA (FDA approved drug products index) at https://www.accessdata.fda.gov/scripts/cder/daf/

3) Pediatric ARV treatment and Perinatal guidelines at https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new-guidelines

Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors

Infants unable to receive oral dosing may receive intravenous dosing

Antiretroviral (ARV) Medications to Avoid for PEP

- Clinicians should not prescribe the following for PEP: Abacavir (ABC; brand name Ziagen), efavirenz (EFV; brand name Sustiva), indinavir (IDV; brand name Crixivan), maraviroc (MVC; brand name Selzentry), nelfinavir (NFV; brand name Viracept), nevirapine (NVP; brand name Viramune), and zidovudine (ZDV; brand name Retrovir).
- ZDV remains a recommended medication for the prevention of perinatal transmission of HIV and for pediatric PEP.
- Providers should be aware that abacavir sulfate (Ziagen, ViiV Healthcare, Brentford, Middlesex, United Kingdom) should not be prescribed in any nPEP regimen. Prompt initiation of nPEP does not allow time for determining if a patient has the HLA-B*5701 allele, the presence of which is strongly associated with a hypersensitivity syndrome that can be fatal.

PEP During Pregnancy or Breastfeeding

- When a significant exposure to HIV has occurred at any time during an individual exposed to HIV's pregnancy or while that individual is breastfeeding a baby, clinicians should initiate PEP with a preferred or alternative regimen.
- Clinicians should advise individuals who may have been exposed to HIV to avoid breastfeeding for 3 months after the exposure.
- Individuals confirmed to be HIV negative may breastfeed.

PEP for an individual who is taking PrEP

On occasion, an individual exposed to HIV who has been taking PrEP may insist on receiving a third ARV medication as PEP despite a clinician's reassurance that it is not necessary. A clinician may reassure a patient who is taking PrEP with daily adherence that no current evidence can support adding an additional ARV after a potential exposure. However, if the individual exposed to HIV has only recently started taking PrEP, has been taking PrEP inconsistently, or has been taking the medications "on-demand," it may be reasonable to consider a 28-day course of 3- drug PEP after a high-risk exposure. Similarly, if the source has virus with known underlying resistance to the components of a PrEP regimen (emtricitabine or tenofovir), offering 3-drug PEP to the individual exposed to HIV should be considered, particularly if the source's viral load is not suppressed (i.e., <200 copies/mL). Lastly, there may be instances where the clinician may have to balance an individual exposed to HIV's level of anxiety with maintaining the therapeutic alliance between the patient and care provider: offering 3-drug PEP in these scenarios may be appropriate to daily PrEP users in rare circumstances, such as high-risk needle sharing exposures or on a case-by-case basis. A request for PEP from a patient who is consistently using PrEP should not be accommodated following an exposure that is evaluated to be low or zero risk.

PEP regimens for Patients who weigh <40kg

- No clinical studies are available to determine the best regimens for HIV PEP in children. The recommendations for drug choices and dosages presented here follow current U.S. Department of Health and Human Services recommendations in Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection, which are based on expert opinion. The recommended regimens reflect experience with ARV combinations that effectively suppress viral replication in children with HIV and with combinations that are well tolerated and increase adherence to PEP. The chosen preferred regimens have demonstrated good potency and tolerability.
- The alternative PEP regimens for children are also based on expert opinion. They all have demonstrated potent antiviral activity. However, the PI-containing regimens are often more difficult to tolerate, secondary to gastrointestinal adverse effects. To improve adherence, clinicians can and should prescribe preemptive antiemetics for anticipated gastrointestinal adverse effects.
- When choosing a PEP regimen, care providers should consider factors that may affect adherence, such as ARV drug intolerance, regimen complexity, expense, and drug availability.

Practitioner Consultation with a Specialist if Recommended

- If consultation is not immediately available, nPEP should not be delayed; changes can be made as needed after nPEP has been initiated. If the source is found to be HIV negative or nonreactive, nPEP should be discontinued. Delaying nPEP therapy in order to obtain resistance test results (genotyping or phenotyping) for the purpose of selecting more specific therapy is not advised. Persons exposed to HIV are frequently unable to complete nPEP regimens due to side effects. Providing prophylactic symptom management can improve adherence.

NCCC nPEP Hotline: 1-888-448-4911

CDC Hotline: 1-800-232-4636

Step Four: Referral, Follow-Up, and Monitoring

All patients receiving nPEP should be re-evaluated within three days of the exposure to review the exposure and available source person data, evaluate adherence and monitor for side effects or toxicities associated with the nPEP regimen. The person exposed to HIV should be evaluated biweekly while receiving nPEP to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.

Monitoring the patient exposed to HIV during nPEP treatment and the follow-up period should be provided by or in consultation with a clinician experienced in managing nPEP. Emergency departments, urgent care centers and other treating health centers should establish linkages with local HIV providers to facilitate easy referral of patients for follow-up care.

Providers who do not have access to a clinician experienced in nPEP should use the HIV Clinician Consultation Center PEPline at 1-888-448-4911 for phone consultation. Hours of operation are Monday through Friday, 9:00am–8:00pm Eastern and weekends 11:00am–8:00pm Eastern.

HIV Seroconversion

If HIV infection develops after an exposure, it will generally occur within two to four weeks of exposure. HIV testing at baseline, 4 weeks, and 12 weeks is recommended after significant exposures, regardless of whether the individual accepts or declines PEP treatment. Point-of-care HIV tests (rapid tests) are less sensitive than laboratory-based HIV tests; therefore, persons exposed to HIV should be tested with laboratory-based HIV tests whenever possible. If NAAT is positive, stop PEP, refer to confirmatory testing and HIV treatment if needed.

Patients acutely infected with HIV will often experience at least some symptoms of the acute retroviral syndrome. Fever and flu-like symptoms are common in acute HIV infection but are nonspecific. Rash, mucocutaneous ulcers, oropharyngeal candidiasis and meningismus are more specific. Symptoms may also include fatigue or malaise, joint pain, headache, loss of appetite, night sweats, myalgias, lymphadenopathy, oral and/or genital ulcers, nausea, diarrhea or pharyngitis. Acute HIV infection is often not recognized in the primary care setting because of the similarity of the symptom complex with that of the flu or other common illnesses.

Recommended Monitoring After Post-Exposure Prophylaxis Initiation

CLINIC VISITS

▶ Baseline	▶ 48 Hours	▶ Week 2	▶ Week 4	▶ Week 12

Follow-ups at 48 hours and 2 weeks may be conducted by telehealth/telephone call.

HIV ANTIGEN/ANTIBODY TEST (RECOMMENDED EVEN IF INDIVIDUAL DECLINES PEP)

▶ Baseline			▶ Week 4	▶ Week 12

SERUM LIVER ENZYMES, BLOOD UREA NITROGEN, CREATININE, COMPLETE BLOOD COUNT (CBC)

▶ Baseline		▶ Weeks 2 and 4 in patients ≥12 years if baseline test results are abnormal or if adverse effects are reported.

PREGNANCY TEST

Only if the individual exposed to HIV is of childbearing capacity

▶ Baseline			▶ Week 4	

HEPATITIS B SURFACE ANTIGEN (HBSAG) AND SURFACE ANTIBODY (ANTI-HBS)

▶ Baseline				▶ Week 12 for age 12 and older

HEPATITIS C VIRUS (HCV) ANTIBODY

▶ Baseline				▶ Week 12

- HCV serology should be performed 6 months after an initial nonreactive test result.
- Liver function panel and HCV antibody test should be performed 6 months after HCV exposure

Referrals

- Mental health/substance abuse may contribute significantly to the risk of subsequent exposures.
- nPEP should be provided with services that address ongoing needs of patient risk behaviors.
- Providers should be aware of local resources for mental health/substance abuse treatment.

National Sexual Assault Telephone Hotline: 1-800-656-HOPE

HIV Hotline for patients in need of HIV-specific support: 1-800-CDC-INFO

- Primary care referrals should also be available, when indicated.

Making Referrals for nPEP follow-up

- Option 1: Each facility or clinic provider performing an examination, including sexual assault exams, should solicit a relationship with a qualified medical provider who is knowledgeable about HIV treatment and nPEP and has the ability to receive patients within three to five days of the initial exam and referral.
- Option 2: The initial facility's health care provider/physician may have the patient return to their facility for follow-up treatment if no other option is available.
- Option 3: If there is not an established relationship and/or no physician available, then sexual assault victims who have been assessed by a physician and have met the criteria for nPEP can be referred to another primary care provider or a local infectious disease physician.

Pharmacy Considerations

Pharmacists play a role in the dispensation of nPEP regimens. In order to ensure more timely access of nPEP medications to patients, providers should be aware that the use of "phone-in" oral prescriptions may result in faster dispensing and avoid situations where drug access might be limited. When nPEP is prescribed to a patient receiving other prescription and non-prescription medications, a complete drug profile review should take place to assess for any drug-drug interactions. No medications should be dispensed as part of an nPEP regimen if all medications are unavailable at the same time.

It is beneficial to coordinate with local pharmacies in determining which ones have nPEP medications in stock or can order them quickly. Providers can discuss the treatment with local pharmacies and the need for an urgent response when prescribing nPEP medications.

Pharmacists with specific questions regarding nPEP therapy should contact the PEP Hotline at (888) 448-4911, Monday through Friday from 9:00am–8:00pm Eastern and weekends from 11:00am–8:00pm Eastern.

Sample HIV nPEP Discharge Instructions

Medical Record No: _____ **Name:** _____

The following tests were conducted today:

- ☐ HIV test (rapid / 4th gen / _____)
- ☐ Pregnancy test
- ☐ CMP
- ☐ CBC
- ☐ Hepatitis B serology _____
- ☐ Hepatitis B serology _____
- ☐ GC/CT
- ☐ Syphilis/RPR
- ☐ eGFR
- ☐ Other_____

The following medications were prescribed today:

☐ **HIV Prophylaxis**

You have been given a _____ day starter pack of medications. You will need to follow up with your primary care physician or an infectious disease physician in less than _____days to receive counseling, blood tests and the remainder of the medication regimen to complete the 28-day dose.

☐ **Treatment for Gonorrhea**

Ceftriaxone (Rocephin) 250 mg IM in a single dose **PLUS**
Azithromycin (Zithromax) 1 gram PO in a single dose

☐ **Treatment for Chlamydia**

Azithromycin (Zithromax) 1 gram PO in a single dose **OR**
Doxycycline 100 mg PO twice a day for 7 days

☐ **Emergency Contraception**

Levonorgestrel (Plan B) 0.75 mg tablets: 1 tablet now and 1 tablet in 12 hours at ____

☐ **Hepatitis B vaccination**

(Recombivax HB) 0.5 ml IM x 1 dose

☐ **Series #1**

☐ **Series #2**

☐ **Series #3**

During my evaluation, it was determined that I may have been exposed to the HIV virus. I have consented to and been prescribed a 28-day nPEP medication regimen that may help prevent transmission of the HIV virus.

I understand that I need a follow up examination (with my clinic/doctor of choice), and I should bring this sheet so that my health care provider will know what treatment I received and can perform tests to be sure that the medications were effective.

I have been advised that during the 12-week follow-up period, I should:

- Use condoms to prevent sexual transmission
- Avoid pregnancy and breastfeeding
- Avoid needle-sharing
- Refrain from donating blood, plasma, organs, tissue or semen

I have been counseled on taking all of the medications as directed. I was counseled on the need to see a doctor/clinician within three (3) days of my exam. If I do not have a primary physician, I need to contact an infectious disease physician or other medical provider to schedule an appointment.

I will be certain to tell the medical facility with whom I am trying to get an appointment that I may have been exposed to HIV, that I have already started the nPEP medications, and that I need to see a physician within three (3) days of starting this medicine.

I will take a copy of this form along with my other discharge instructions to my medical provider.

Patient signature: _____ Date: _____

Modified from Plan of Action for Victims of Sexual Assault, State of Kentucky

nPEP Billing and Coding Guide

Recommended ICD-10-CM Codes: Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)

VISITS

All office visits must include a principal diagnosis/first-listed condition to be billable. Z20.6, bolded below, is classified as an acceptable principal diagnosis in the ICD-10-CM system. Always include Z20.6 when coding PrEP or PEP visits. If an insurer requires additional coding clarifying a patient's risk, Z20.2 (sexual exposure risk) and F19.20 (injection drug use exposure risk) can be added. These codes avoid the use of the Z72.x codes that are considered stigmatizing because they indicate problems related to lifestyle.

TESTS

HIV, STI, HCV and other tests associated with PrEP and PEP are related to the patient's ongoing risk of infection, even if the patient is asymptomatic. Screening tests are ordered at initial visit. Subsequent visits use 'contact with' codes. Tests which are ordered to evaluate the patient for conditions potentially associated with long-term use of PrEP medication should include the code Z79.899.

PrEP-Related Codes — Initial Visit

Coding for:	ICD-10 Code	Description
Visit	**Z20.6**	**Contact with and (suspected) exposure to HIV**
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Initial Tests	Z01.812	Encounter for pre-procedural laboratory examination (Applicable to blood and urine tests prior to treatment or procedure)
	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
	Z11.4	Encounter for screening for human immunodeficiency virus
	Z11.59	Encounter for screening for other viral diseases*

PrEP-Related Codes — Second and Subsequent Visits

Coding for:	ICD-10 Code	Description
Visit and Tests	**Z20.6**	**Contact with and (suspected) exposure to HIV**
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z79.899	Other long-term drug therapy
	Z20.5	Contact with and (suspected) exposure to viral hepatitis*

PEP-Related Codes — Initial and Subsequent Visits

Coding for:	ICD-10 Code	Description
Visit and Tests	**Z20.6**	**Contact with and (suspected) exposure to HIV**
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z20.5	Contact with and (suspected) exposure to viral hepatitis

*WHEN ORDERING HEPATITIS C TESTS FOR PATIENTS INSURED THROUGH MEDICARE:

Medicare covers annual hepatitis C screening only for **high-risk individuals**	▶ A single, once-in-a-lifetime screening test is covered for individuals born from 1945 through 1965 who do not meet the high-risk definition. ▶ Per Medicare guidance, the initial encounter/test requisition for hepatitis C tests must include diagnosis code Z72.89 (Other problems related to lifestyle). ▶ Follow-up encounters/tests for annual hepatitis C testing should include diagnosis codes Z72.89 and/or F19.20 (Unspecified drug dependence). *Consult Medicare guidance documents for specific billing details.*

nPEP Payment Options

Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

Chapter 39 of the Laws of 2012 amending Section 2805i of Public Health Law requires hospitals to provide the first seven days of medication to victims of sexual assault. Prescriptions must be given for the remaining 21 days.

Medicaid	PEP is covered.
Private Insurance	PEP coverage is based on plan. Large co-pay may be a consideration. Maryland Governor's Office of Crime Prevention, Youth, and Victim Services: Sexual Assault Reimbursement Unit (SARU) may reimburse copays of a victim who submits an eligible application with the agency. Co-payment cards are available from the manufacturers. ▶ Gilead: 1-877-505-6986 ▶ Merck: 1-855-834-3467 or https://www.isentress.com ▶ ViiV Healthcare: 1-866-747-1170 or https://myviivcard.com
Insured, but does not use insurance	A victim may decline to provide insurance information if he/she believes provision of that information would substantially interfere with his or her personal privacy or safety. A victim may ask the provider to directly bill the SARU for the Sexual Assault Forensic Medical Exam (SAFE), including the first seven days of medication.
Uninsured/ Underinsured	SARU may be directly billed as above and the victim may apply to SARU for expenses beyond the FRE, including a prescription for the remaining 21 days.
Maryland Governor's Office of Crime Prevention, Youth, and Victim Services	The SARU is responsible for establishing a reimbursement process and reviewing claims for SAFEs and associated services as outlined in Maryland statute and regulations. These services include emergency hospital treatment, follow-up care related to the rape, sexual assault, or child sexual abuse, and medications such as HIV Prophylaxis (nPEP).

For All Other Non-Occupational Exposures in any Health Care Setting

Medicaid	PEP is covered.
Private Insurance	PEP coverage is based on plan. Co-payment cards are available from the manufacturers. ▶ Gilead: 1-877-505-6986 ▶ Merck: 1-855-834-3467 or https://www.isentress.com ▶ ViiV Healthcare: 1-866-747-1170 or https://myviivcard.com
Uninsured/ Underinsured	▶ Treating institution provides immediate access to drugs. ▶ Begin application process for Medicaid, if appropriate. (Coverage is not guaranteed). ▶ Explore the Patient Assistance Programs from pharmaceutical companies. ▶ Contact your human service/social work department for special funds.
Patient Assistance Programs	Common Patient Assistance Program Application (HIV): https://files.hiv.gov/s3fs-public/cpapa-form.pdf HIV meds are listed by company with instructions on how to submit the application. You may need to apply to more than one company depending on the regimen chosen. *Please see specific application processes on the following pages for Gilead, Merck, and ViiV Healthcare.*

Patient Assistance Programs

Gilead Patient Assistance

- **Download form at** https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf
- **Fax a letter of medical necessity to 1-800-216-6857 and include:**
  - Indicate prescribing PEP: this will expedite processing.
  - Patient's name, date of birth, address, and phone number.
  - Therapy needed.
  - Date of exposure.
  - Provider's address, phone number, NPI#, and signature.
  - If patient has already started therapy, date therapy started.
  - If patient resides in U.S.
  - Household size.
  - Household income must be less than 500% FPL based on household size.
  - Patient consent, if necessary provider consent will suffice.
- **Call 1-800-226-2056 and notify them you have a patient who needs PEP.**
  - Tell them you faxed in a letter of medical necessity.
  - Give them time of fax.
  - Number of pages.
  - Your fax number.
  - Will take 5-10 minutes.
  - Hours: Monday through Friday 9:00am-8:00pm Eastern.
- **They will give you a voucher number to place on the prescription.** The patient may go to the pharmacy to have the prescription filled with no out of pocket expenses.
- **For co-payment assistance call 1-800-226-2056** Monday through Friday 9:00am–8:00pm Eastern. Patient is given an authorization number to present with the prescription and other insurance at the pharmacy.

Merck Patient Assistance Program

- **Locate form at** https://www.needymeds.org
  - In "Drug Search" text box, enter "Isentress."
  - Select the "Isentress (raltegravir)" option; then the Patient Assistance Programs icon.
  - Select "Patient Assistance Program Enrollment Form" (https://www.needymeds.org/papforms/merpae0106.pdf).
  - Print and fill out.
  - Indicate prescribing PEP—this will expedite processing.
  - Fax to 1-866-410-1913. You may send fax at any time. Hours: Monday through Friday 6:00am-3:00pm Pacific.
- **Call 800-727-5400 one to two hours after sending fax.**
- **Will send medications to provider or patient as indicated on form**
  - If received by 12:30 PST, will have overnight delivery. (about 24 hours)
  - If received after 12:30 PST, will have next day delivery. (about 48 hours)
- **For copayment assistance, call 1-855-834-3467 or visit** https://www.isentress.com
  - For online application and coupon redemption
  - For presentation with the prescription and insurance coverage at the pharmacy.

ViiV Healthcare Patient Assistance Program

For assistance with costs for TIVICAY® (dolutegravir) Oral Tablets. Non Medicare Part D patients who need dolutegravir that same day can be enrolled by phone.

- **Complete the Application**
  - Complete, print, and sign the two-page ViiV Healthcare Patient Assistance Program enrollment application available at https://www.viivconnect.com.
  - For help completing the application, call ViiV Healthcare Patient Assistance Program at 1-844-588-3288.
- **Select an Advocate to enroll the patient by phone.** This person may be a health care worker, social worker, case worker, or anyone involved in the delivery of the patient's healthcare who is not a family member or friend.
  - Call 1-844-588-3288 Monday through Friday 8:00am–11:00pm Eastern to find out if the patient is eligible.
  - Indicate prescribing PEP — this will expedite processing.
  - During the enrollment phone call, the Advocate will be told whether or not the patient qualifies for the program.
  - Patient income verification can be accepted verbally.
  - Submit the application and prescription via fax.
  - Faxed prescriptions must be sent directly from the prescriber's office in order to be processed without any delay.
- **The initial fill of the dolutegravir prescription can be obtained at a local retail pharmacy.** The patient must bring the ViiV Healthcare Patient Assistance Program voucher (found on the application form, to be given to the patient only after phone enrollment is completed); and the signed original prescription (up to 30-day supply) to the pharmacy.
- **Once the patient's application and supporting documentation have been received and approved, the patient will receive medicine through the mail order pharmacy** and will no longer be eligible to obtain medicine via a retail pharmacy.
- **For copayment assistance, call the Help Desk at 1-844-588-3288** Monday through Friday 8:00am–11:00pm Eastern or visit https://myviivcard.com. Coupon can be printed from website after answering a brief questionnaire, or mailed to the patient if calling the Help Desk.

Sample Letter of Medical Necessity for use in obtaining Gilead's Truvada

Date: _____

To Whom It May Concern,

This letter is written on behalf of patient, _____, DOB ___/ ___/ ___, to support and confirm medically the necessity of treatment for post-exposure prophylaxis.

This patient was exposed to the human immunodeficiency virus (HIV) on _____ (date) at _____ (time) a.m. or p.m.

Please approve expeditiously the immediate coverage of emtricitabine/tenofovir (Truvada®) so that the patient may begin treatment within the recommended 72-hour timeframe of potential HIV exposure.

Sincerely,

_____

Resources

National Clinician Consultation Center (NCCC)

- Hours of operation for non-occupational PEP consultation are Monday through Friday 9:00am–8:00pm Eastern, and weekends & holidays 11:00am–8:00pm Eastern.
- (888) 448-4911
- https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis
- PEP resources: https://nccc.ucsf.edu/clinical-resources/pep-resources

Centers for Disease Control and Prevention (CDC)

- Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV— United States, 2016: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
- PEP HIV Basics: https://www.cdc.gov/hiv/basics/pep.html
- Get Tested — National HIV, STD, and Hepatitis Testing: https://gettested.cdc.gov

NASTAD

- PrEP/PEP Assistance programs: https://nastad.org/prep-access/prep-assistance-programs
- Billing Codes: https://nastad.org/resources/billing-coding-guide-hiv-prevention-prep-screening-and-linkage-services

Maryland Governor's Office of Crime Prevention, Youth, and Victim Services

- Financial Assistance: http://goccp.maryland.gov/victims/saru/

Maryland SAFE Programs

(UPDATED SEPTEMBER 2021)

FNE-A: Individuals age 13 and older

FNE-P: Individuals age 12 and younger

*indicates a SAFE Program with limited hours

**Program provides medical screening & transportation assistance to other local SAFE Program for evidence collection

Allegany/Garrett County

UPMC Western Maryland
FNE-P and FNE-A
12500 Willow Brook Rd.
Cumberland, MD 21502
(240) 964-1333

Anne Arundel County

Anne Arundel Medical Center
FNE-A
2001 Medical Pkwy.
Annapolis, MD 21401
(443) 481-1200

North Anne Arundel County

Baltimore Washington Medical Center
FNE-P and FNE-A
301 Hospital Drive
Glen Burnie, MD 21061
(410) 787-4565

Baltimore City

Mercy Medical Center
FNE-A
345 St. Paul Place Baltimore, MD 21202
(410) 332-9494

University of Maryland Medical Center
Pediatric Emergency Department – Under 13 years old
Exam by ER physician
22 S. Greene Street.
Baltimore, MD 21201
(410) 328-6335

Baltimore County

Greater Baltimore Medical Center
FNE-P and FNE-A
6701 Charles Street
Baltimore, MD 21204
(443) 849-3323

Calvert County

Calvert Health Medical Center
FNE-P and FNE-A
100 Hospital Road
Prince Frederick, MD 20678
(410) 535-8344

Caroline County

UM Shore Medical Center of Easton
FNE-P and FNE-A
219 S. Washington Street
Easton, MD 21601
(410) 822-1000 ext. 5557

Carroll County

Carroll Hospital Center
FNE-P and FNE-A
200 Memorial Ave.
Westminster, MD 21157
Forensics Department: (410) 871-6655 ER:
(410) 876-3000

Cecil County

Union Hospital
FNE-A
106 Bow Street
Elkton, MD 21921
(410) 406-1370

Charles County**

UM Charles Regional Medical Center
FNE-P and FNE-A
701 East Charles Street
LaPlata, MD 20646
(301) 609-3000

Dorchester County

UM Shore Medical Center of Dorchester
FNE-P and FNE-A
300 Bryn Street
Cambridge, MD 21613
(410) 822-1000 ext. 8361

Frederick County
Frederick Health
FNE-P and FNE-A
400 West 7th Street
Frederick, MD 21701
(240) 566-HELP (4357)

Harford County
Harford Memorial
FNE-P and FNE-A
501 South Union Avenue
Havre de Grace, MD 21078
(443) 843-5500

Howard County
Howard County General Hospital
FNE-P and FNE-A
5755 Cedar Lane
Columbia, MD 21044
(410) 740-7777

Kent County
UM Shore Medical Center Chestertown
FNE-P and FNE-A
100 Brown Street
Chestertown, MD 21620
(410) 778-3300

Montgomery County
Shady Grove Adventist Healthcare Center
FNE-P and FNE-A
9901 Medical Center Drive
Rockville, MD 20850
(240) 826-6225

Prince George's County
UM Capital Region Medical Center
FNE-P and FNE-A
901 N. Harry S. Truman Drive Largo,
MD 20774
(240) 677-2337

Queen Anne County
UM Medical Center Chestertown
FNE-P and FNE-A
100 Brown Street
Chestertown, MD 21620
(410) 778-3300

St. Mary's County*
St. Mary's Hospital
FNE-P and FNE-A
25500 Point Lookout Road
Leonardtown, MD 20650
(301) 475-8981

Talbot County
UM Shore Medical Center of Easton
FNE-P and FNE-A
219 S. Washington Street
Easton, MD 21601
(410) 822-1000 ext. 5557

Washington County*
Meritus Medical Center
FNE-P and FNE-A
11116 Medical Campus Road Hagerstown,
MD 21742
(301) 790-8300

Wicomico/Somerset County
TidalHealth Peninsula Regional
FNE-P and FNE-A
100 East Carroll Street
Salisbury, MD 21801
(410) 543-7100

Worcester
Atlantic General Hospital
FNE-P and FNE-A
9733 Healthway Drive
Berlin, MD 21811
(410) 641-1100

Providers in Maryland where PEP is available

AIDS Healthcare Foundation
11 E. Lexington St., Suite 100
Baltimore, MD 21202
(833) 243-7411
Office Hours: Tuesday and Thursday
1:00pm–5:00pm

Allegany County Health Department
12501 Willowbrook Road
Cumberland, MD 21502
(301) 759-5138
Office Hours: Tuesday 8:00am–10:45am
and 1:00pm–2:30pm (Walk-in)

Bartlett Specialty Clinic
1717 East Monument St.
Baltimore, MD 21287
(410) 614-7175
Office Hours: Monday through Friday
8:00am–5:00pm

BCHD Druid STD Clinic PrEP Initiative
1515 North Ave.
Baltimore, MD 21217
(410) 396-0176
Office Hours: Wednesday and Friday
8:30am–4:30pm

BCHD Eastern STD Clinic PrEP Initiative
1200 E. Fayette St
Baltimore, MD 21205
(410) 396-9410
Office Hours: Monday and Tuesday
8:30am–4:30pm; Thursday 8:30am–1:00pm

Center for Child and Adolescent Health
Johns Hopkins Harriet Lane
200 North Wolfe Street, Rubenstein Child Health Suite 3145
Baltimore, MD 21287
(443) 467-6422
Office Hours: Monday through Friday
9:00am–5:00 pm

Chandralekha Banerjee, MD
5601 Loch Raven Blvd
Baltimore, MD 21239
(443) 444-4723
Office Hours: Tuesday and Friday 8:30am–1:00pm, Wednesday 8:30am–12:00pm, 1:00pm–3:00pm

Chase Brexton – Anne Arundel County Center
200 Hospital Dr, Suite 300
Glen Burnie, MD 21061
(410) 837-2050
Office Hours: Monday through Friday
8:30am–5:00 pm

Chase Brexton – Columbia Center
5500 Knoll North Drive, Suite 370
Columbia, MD 21045
(410) 884-7831
Office Hours: Monday through Thursday
8:00am–8:00pm, Friday 8:00am–5:00pm

Chase Brexton – Easton Center
8221 Teal Drive, Suite 202
Easton, MD 21061
(866) 260-0412
Office Hours: Monday through Friday
8:30am–5:00pm

Chase Brexton – Randallstown Center
3510 Brenbrook Drive
Randallstown, MD 21133
(410) 837-2050
Office Hours: Monday through Thursday
8:00am–8:00pm; Friday 8:00–5:00pm

Chase Brexton – Mount Vernon
1111 North Charles St
Baltimore, MD 21201
(410) 837-2050
Office Hours: Monday through Thursday
8:00am–8:00pm; Friday 8:00am–5:00pm

Dorchester County Health Department
3 Cedar Street
Cambridge, MD 21613
(410) 228-3223
Office Hours: Monday through Friday
8:00am–4:00pm

Dr. Andrew Cantanzaro
7600 Carroll Avenue
Takoma Park, MD 20912
(301) 891-6100
Office Hours: Thursday 8:00am–12:00pm

Dr. Ashebir Woldeabezgi
11637 Terrace Dr, Suite 103
Waldorf, MD 20602
(301) 374-9725
Office Hours: Monday and Wednesday
10:00am–2:00pm

Dr. Kelly Russo
9220 Springhill Lane
Greenbelt, MD 20770
(240) 624-2503
Office Hours: Monday through Friday
8:30am–5:00pm

Infectious Diseases Outpatient Clinic, Bayview Medical Center
4940 Eastern Ave
Baltimore, MD 21224
(410) 550-9085
Office Hours: Tuesday 1:00pm–5:00pm

JAI Medical Center
1235 Monument St
Baltimore, MD 21202
(410) 327-5100
Office Hours: Monday through Friday
9:00am–6:00pm

Laura Simpkins FNP
3120 Erdman Ave
Baltimore, MD 21213
(410) 276-7226
Office Hours: Monday 10:00am–7:00pm;
Tuesday through Friday 8:00am–5:00pm

Montgomery Infectious Disease Associates
8630 Fenton Rd, Suite 700
Silver Spring, MD 20910
(301) 588-2525
Office Hours: Monday through Friday
9:00am–5:00pm

University of Maryland Emergency Department
22 South Greene Street
Baltimore, MD 21201
(410) 328-9595
Office Hours: Everyday 24/7

Washington County Health Department
1302 Pennsylvania Avenue
Hagerstown, MD 21742
(240) 313-3296
Office Hours: First and third Wednesdays
1:00pm–3:00pm

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Maryland
DEPARTMENT OF HEALTH

The Maryland Department of Health has engaged with HealthHIV, a national capacity building organization, to launch Alive! Maryland to build the capacity of Maryland's HIV, viral hepatitis, STIs, and harm reduction workforce to improve health for all Marylanders.

Learn more at AliveMaryland.org.

HealthHIV

HealthHIV is a national non-profit working with organizations, communities, and health care providers to advance effective prevention, care, and support for people living with, or at risk for, HIV and HCV through education and training, technical assistance and capacity building, advocacy, and health services research and evaluation.

Learn more at HealthHIV.org.

Alive! MARYLAND
BUILDING CAPACITY TO IMPROVE HEALTH

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