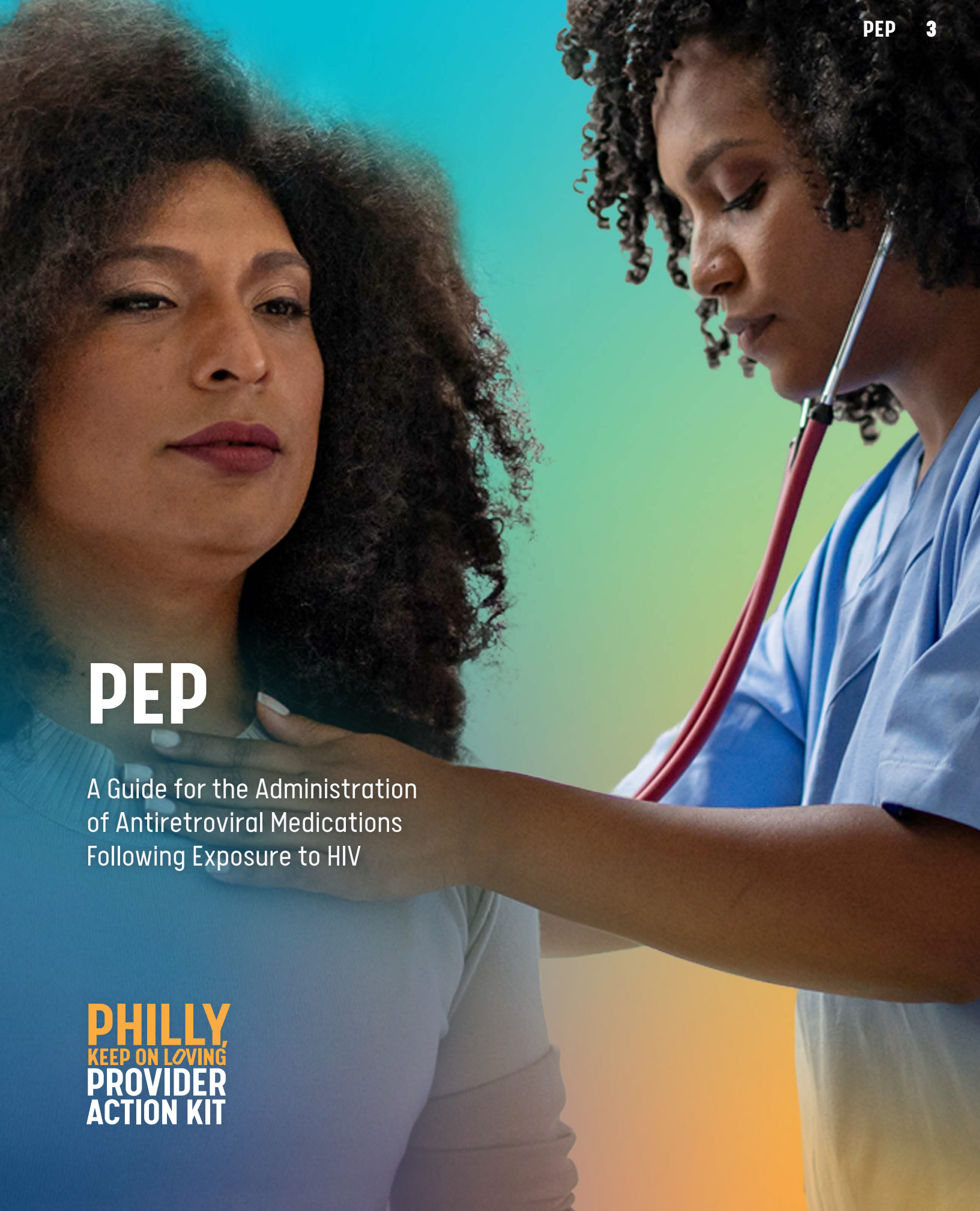

PEP

A Guide for the Administration of Antiretroviral Medications Following Exposure to HIV

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PROVIDER ACTION KIT

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Department of Public Health
CITY OF PHILADELPHIA

City of Philadelphia Department of Public Health
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PEP

This HIV Post Exposure Prophylaxis (PEP) booklet aims to provide clinicians with a comprehensive understanding of this critical intervention strategy. PEP refers to the administration of antiretroviral medications following potential exposure to the human immunodeficiency virus (HIV). Its primary goal is to prevent the establishment of HIV infection in a person who has experienced a non-occupational exposure that presents substantial risk for HIV transmission within the last 72 hours.

This booklet serves as a guide for healthcare providers, equipping them with the necessary knowledge to assess the eligibility of individuals for PEP, initiate timely treatment, and monitor patients throughout the course of therapy. By following evidence-based guidelines, healthcare professionals can play a pivotal role in reducing the risk of HIV transmission and improving patient outcomes.

What is nPEP?

nPEP (non-occupational post exposure prophylaxis) is the use of antiretroviral therapy following a known or potential exposure to HIV that occurred through sexual contact or through injection drug use.[1]

PEP Effectiveness

- Studies, retrospective reviews, and expert opinion have suggested that daily adherence to a three-drug HIV PEP regimen of 28 days initiated within 72 hours of the potential HIV exposure is effective in preventing HIV infection.[2,4,5]

- Cases of new HIV diagnoses despite use of PEP is attributed to delayed initiation beyond 72 hours or low daily adherence to regimen.[2,4,5]

PEP is for Emergency Situations

- It's important to note that PEP should not be considered a substitute for regular use of other HIV prevention methods.

- PEP is not intended for individuals who may be frequently exposed to HIV.

- If an individual is at ongoing risk for HIV due to repeated exposures, it is advisable to consult a healthcare provider about PrEP (pre-exposure prophylaxis).

Type of Exposures

- Post-exposure prophylaxis should be recommended, and immediate medical attention should be sought, when an individual reports a known or potential exposure to HIV within the past 72 hours.[1]
- Situations that warrant an immediate referral for PEP include:
  - Condomless receptive or insertive vaginal or anal intercourse with a partner living with HIV or a partner whose status was unknown, including intercourse that involved condom slippage or breakage and
  - Needle-sharing and
  - Injuries with exposure to blood or other potentially infected fluids from a source known to be HIV-infected or HIV status is unknown (including needlesticks with a hollow-bore needle, accidents, etc.)[1]
- For persons presenting with wounds or needlestick injuries:
  - The site should be washed with soap and water, avoiding irritation of the skin.
  - The wound should not be "milked" or squeezed. Squeezing the wound may promote hyperemia and inflammation at the wound site, potentially increasing systemic exposure to HIV if present in the contaminating fluid. [1]
- Lower risk exposures that require evaluation by a clinical provider on a case-by-case basis include:
  - Oral-vaginal contact (receptive and insertive)
  - Oral-anal contact (receptive and insertive)
  - Receptive penile-oral contact with or without ejaculation
  - Insertive penile-oral contact with or without ejaculation[1]
- The level of risk in these situations increases with the presence of blood, genital ulcers, STDs (sexually transmitted diseases), or non-intact skin or mucus membranes.[1]

According to CDC PEP guidelines, individuals who report an ongoing risk of HIV exposure (e.g., through injection drug use or condomless sex) or who have used more than one course of PEP in the past year should be provided with resources for HIV prevention, including an assessment for PrEP eligibility.

For More Information

- Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016
  bit.ly/4dSZOHd
- Clinical Guidance for PEP
  bit.ly/3SZp2k1
- PEPline: Expert consultation for issues and any other guidance on nonoccupational PEP can be obtained by calling the National Clinician Consultation Center's Post-Exposure Prophylaxis PEPline at 888-448-4911

Prescribing PEP

This guide provides an evidence review, patient management guidelines, laboratory testing, recommended antiretroviral nPEP regimens, financial assistance for nPEP medication, and considerations for special populations.

Baseline Labs and Monitoring

- Baseline labs should be obtained at initial visit for PEP and monitored after completion of PEP regimen. See table on the following page.[3]
- Attempts should be made to also test the person believed to be the source of the possible exposure if possible.[3]

For More Information

- Philly's 24/7 PEP hotline: 833-933-2815

Recommended Schedule of Laboratory Evaluations of Source and Exposed Patients for Providing nPEP with Preferred Regimens[3]

Test	Source Baseline	Baseline	4–6 Weeks After Exposure	3 Months After Exposure	6 Months After Exposure
		*For all patients considered for or prescribed nPEP for **any exposure***			
HIV Ag/Ab testing[a] (or antibody testing if Ag/Ab test unavailable)	■	■	■	■	■ [b]
HBV serology, including: HBV surface antigen HBV surface antibody HBV core antibody	■	■	—	—	■ [c]
HCV antibody test	■	■	—	—	■ [d]
		For all patients considered for or prescribed nPEP for sexual exposure			
Syphilis serology[e]	■	■	■	—	■
Gonorrhea[f]	■	■	■ [g]	—	—
Chlamydia[f]	■	■	■ [g]	—	—
Pregnancy[h]	—	■	■	—	—
		For patients prescribed: TDF + F + RAL or TDF + F + DTG			
Serum creatinine (for calculating estimated creatinine clearance[i])	—	■	■	—	—
Alanine transaminase, aspartate aminotransferase	—	■	■	—	—
		For all patients with HIV infection confirmed at any visit			
HIV viral load	■	■ [j]	■ [j]	■ [j]	■ [j]
HIV genotypic resistance	■	■ [j]	■ [j]	■ [j]	■ [j]

a. Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

b. Only if HCV infection was acquired during the original exposure; delayed HIV seroconversion has been seen in people who simultaneously acquire HIV and HCV infection.

c. If exposed person susceptible to HBV at baseline.

d. If exposed person susceptible to HCV at baseline.

e. If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment.

f. Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification testing. For patients diagnosed with a chlamydia or gonorrhea infection, retestir 3 months after treatment is recommended. Comprehensive STI testing and treatment guidelines are available from CDC: cdc.gov/std/treatment-guidelines/default.htm.

- Screening of transgender and gender-diverse patients should be based on anatomy and sexual behaviors and exposure. Access CDC's full screening recommendations: cdc.gov/std/treatment-guidelines/screening-recommendations.htm.
- For men or people assigned male at birth reporting insertive vaginal, anal, or oral sex, a urine specimen (preferred) or urethral swab should be tested for chlamydia and gonorrhea.
- For women or people assigned female at birth reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For any patient reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For any patient with urogenital or rectal gonorrhea reporting receptive oral sex, pharyngeal testing for gonorrhea should be performed. If chlamydia is identified while screening for pharyngeal gonorrhea, provide appropriate treatment. Review CDC's guidelines for treating gonococcal infections: cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm.

g. If not provided presumptive treatment at baseline or if symptomatic at follow-up visit.

h. If a woman or person assigned female at birth of reproductive age, not using effective contraception, and with vaginal exposure to semen.

i. 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

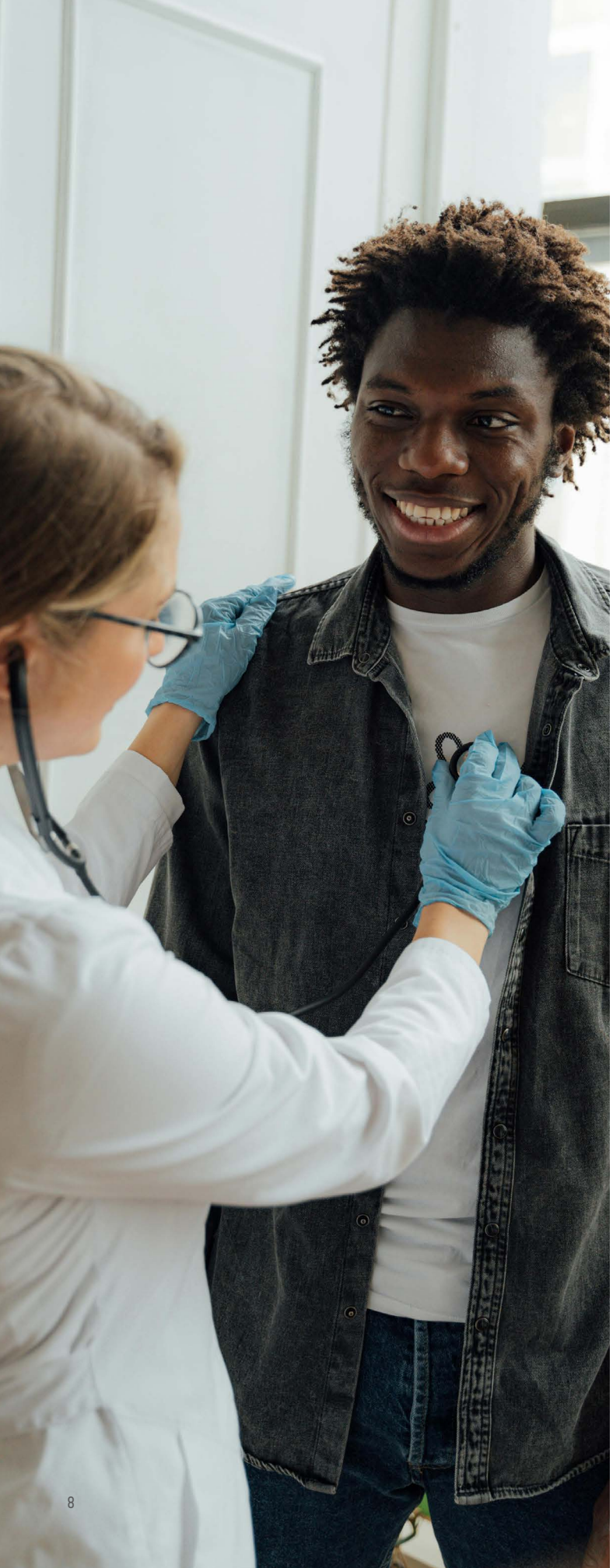
j. At first visit where determined to have HIV infection.

Preferred and Alternative Antiretroviral Medication 28-day Regimens for nPEP[a,b]

AGE GROUP	APPROACH	MEDICATION
Adults and adolescents aged ≥13 years, including pregnant women, with normal renal function (creatinine clearance ≥60 mL/min)	**Preferred**	A three-drug regimen consisting of tenofovir DF 300mg **and** fixed dose combination emtricitabine 200mg (Truvada[c]) once daily **with** raltegravir 400mg twice daily **or** dolutegravir 50mg once daily
	Alternative	A three-drug regimen consisting of tenofovir DF 300mg **and** fixed dose combination emtricitabine 200mg (Truvada) once daily **with** darunavir 800mg (as two 400mg tablets) once daily **and** ritonavir[b] 100mg once daily
Adults and adolescents aged ≥13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A three-drug regimen consisting of zidovudine **and** lamivudine, with both doses adjusted to degree of renal function **with** raltegravir 400mg twice daily **or** dolutegravir 50mg once daily
	Alternative	A three-drug regimen consisting of zidovudine **and** lamivudine, with both doses adjusted to degree of renal function **with** darunavir 800mg (as two 400mg tablets) once daily **and** ritonavir[b] 100mg once daily
Children aged 2-12 years	**Preferred**	A three-drug regimen consisting of tenofovir DF, emtricitabine, and raltegravir, with each drug dosed to age and weight[d]
	Alternative	A three-drug regimen consisting of zidovudine **and** lamivudine **with** raltegravir **or** lopinavir/ritonavir[b], with raltegravir and lopinavir/ritonavir dosed to age and weight[d]
	Alternative	A three-drug regimen consisting of tenofovir DF **and** emtricitabine **and** darunavire/ritonavir[b], with each drug dosed to age and weight
Children aged 3-12 years	Alternative	A three-drug regimen consisting of tenofovir DF **and** emtricitabine **and** darunavir[d]/ritonavir[b], with each drug dosed to age and weight
Children aged 4 weeks[e]-<2 years	**Preferred**	A three-drug regimen consisting of zidovudine oral solution **and** lamivudine oral solution **with** raltegravir **or** lopinavir/ritonavir[b] oral solution (Kaletra[f]), with each drug dosed to age and weight
	Alternative	A three-drug regimen consisting of zidovudine oral solution **and** emtricitabine oral solution **with** raltegravir **or** lopinavir/ritonavir[b] oral solution (Kaletra[f]), with each drug dosed 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.

a. These recommendations do not reflect the current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.
b. 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 "three-drug" regimens.
c. Gilead Sciences, Inc., Foster City, California.
d. Darunavir is only FDA-approved for use among children aged ≥ 3 years.
e. Children should have attained a postnatal age of ≥ 28 days and postmenstrual age (i.e., first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks.
f. AbbVie, Inc., North Chicago, Illinois.



Paying for PEP

- Many insurance providers cover PEP.
- If PEP is obtained through an emergency room, an individual may be given the first dose at the time of their visit, along with a few days' supply. This will give them time to fill the prescription for the complete treatment course.
- If an individual does not have insurance, their provider may be able to assist them with applying for medication assistance programs for PEP.
- Enrollment applications that will be useful in applying for medication assistance programs are:
  - Gilead's Advancing Access Form services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf, and
  - NASTAD'S Patient Assistance Tool nastad.org/resources/pharmaceutical-company-patient-assistance-programs-and-cost-sharing-assistance-programs
  - Resources for Accessing nPEP files.hiv.gov/s3fs-public/2023-10/PAP-CAP-Resources-for-Accessing-nPEP.pdf

Transitioning PEP to PrEP

- Before completion of the patient's 28-day PEP regimen, clinicians should assess patient's interest in PrEP for ongoing HIV prevention.[1]
- Negative HIV status needs to be confirmed prior to switching from PEP to PrEP, in addition to other baseline PrEP labs (see PrEP booklet). Otherwise, there is no contraindication to begin PrEP or need for a gap at the conclusion of the PEP regimen to start PrEP.[1]
- Clinicians should discuss with their patient the importance of continuing adherence with PrEP regimen and changes to their medications when switching from PEP to PrEP.[1]

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