



FSHP 60th Annual Meeting

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Needle-stick to Next Steps: Occupational and Nonoccupational HIV Postexposure Prophylaxis Guideline Updates

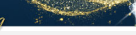
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Abbreviations

Common Terms PEP - Post-Exposure Prophylaxis oPEP - Occupational Post-Exposure Prophylaxis nPEP - Nonoccupational Post-Exposure Prophylaxis PrEP - Pre-Exposure Prophylaxis U=U - Undetectable = Untransmittable Medication Classes ARV - Antiretroviral INSTI - Integrase Strand Transfer Inhibitor NRTI - Nucleoside Reverse Transcriptase Inhibitor PI - Protease Inhibitor	Specific Medications BIC - Bictegravir DTG - Dolutegravir RAL - Raltegravir FTC - Emtricitabine TAF - Tenofovir Alafenamide TDF - Tenofovir Disoproxil Fumarate 3TC - Lamivudine CAB - Cabotegravir LPV/r - Lopinavir/ritonavir DRV/r - Darunavir/ritonavir
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Presentation Objectives

1. Identify first line HIV PEP medications (including pharmacy technician)
2. Differentiate between occupational and nonoccupational HIV exposures (including pharmacy technician)
3. Compare recommended first-line and alternative HIV PEP regimens
4. Evaluate common adverse effects associated with first-line PEP medications
5. Assess safe and effective PEP options for pregnancy, breastfeeding, drug–drug interactions, and renal impairment

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Why This Matters Now



The timeline shows key milestones in HIV prevention:

- 1990:** CDC suggests use of zidovudine for PEP
- 1996:** CDC recommends zidovudine for PEP
- 1997:** Case control study shows zidovudine PEP reduces HIV transmission risk by 81%
- 1998:** CDC recommends risk-based 2-drug (zidovudine and 3-drug expanded) regimens for PEP
- 2001:** CDC issues guidance for occupational exposures to HIV, HCV, HBV
- 2005:** CDC updates basic and expanded regimens for PEP
- 2013:** CDC recommends using 3-drug INST-based regimen when PEP indicated

Since 2013 ...

- 2013
- Expansion of PrEP
- 2018
- BIC/TAF/FTC approved
- 2019
- PARTNER Study U = U
- Expansion of PrEP use
- 2021
- Long-acting PrEP

FSHP 60th Annual Meeting, November 14-15, 2023, National HIV Curriculum, University of Washington, Updated December 1, 2023. Accessed March 2024. <https://www.fsHP.org/60th-annual-meeting>

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Why This Matters Now

- **Two major simultaneous guideline releases in 2025:**
 - CDC MMWR nPEP Guidelines (May 2025)
 - First update since 2016
 - 2025 US PHS oPEP Guidelines
 - First update since 2013, published in *Infection Control & Hospital Epidemiology*

- **Key drivers of both updates**
 - Newer ARV agents
 - Updated HIV testing windows
 - U=U (Undetectable = Untransmittable) science
 - Growing PrEP use among patients and HCP

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DISTINGUISHING
oPEP VS. nPEP

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oPEP vs. nPEP: Who Are We Treating?

	oPEP	nPEP
Population	Healthcare personnel (HCP)	General public
Exposure Route	Needlestick, sharps, blood/fluid splash	Sexual contact, injection drug use, human bites, splash
Regulatory basis	OSHA-mandated provision	Clinician-initiated
Applicable Guideline	2025 PHS/CDC (ICHE)	2025 CDC MMWR

Author: AD, Gross PL, Baruch A, et al. 2025 US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2025;149(1):1-11. doi:10.1017/S0950268824000047
Tanner MD, Weiss P, Carter RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV — CDC recommendations, United States, 2025. MMWR Recomm Rep. 2025;74(3):1-8.

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Occupational Exposure Scenarios (oPEP)

When to Initiate oPEP:

- Percutaneous injury (needlestick, scalpel, hollow-bore needle)
- Mucous membrane splash (eyes, nose, mouth)
- Non-intact skin contact with blood/infectious body fluids
- Primary prevention of occupational exposures remains the most important strategy, grounded in Standard Precautions
- Provision of PEP after occupational exposures is required by OSHA

Key 2025 oPEP Update :

Shared Decision-Making

- Updated guidelines recommend that the exposed healthcare personnel be included in the decision of whether to begin PEP
- Use shared clinical decision-making involving the exposed HCP when deciding whether to forego initiation of PEP or discontinue PEP early when the source has an undetectable serum viral load

Author: AD, Gross PL, Baruch A, et al. 2025 US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2025;149(1):1-11. doi:10.1017/S0950268824000047

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Nonoccupational Exposure Scenarios (nPEP)

Decision Algorithms by Exposure Type - Three decision pathways from 2025 CDC MMWR:

- Sexual exposure
 - Anal/vaginal intercourse without a condom is higher risk
 - Oral-genital contact without a condom generally does not require nPEP
- Injection drug use
 - Shared needles/equipment with a known HIV-positive source with unknown viral suppression
- Other exposures
 - Blood/infectious fluid splash to non-intact skin/mucous membranes, human bites, community needlestick injuries

nPEP NOT recommended when:

- The source has HIV with sustained viral suppression, or the exposure presents no substantial risk for HIV transmission
- Exposure to body fluids not associated with HIV transmission (tears, sweat, urine, nasal secretions, saliva)

Tanner MD, Weiss P, Carter RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV — CDC recommendations, United States, 2025. MMWR Recomm Rep. 2025;74(3):1-8.

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PEP REGIMENS
FIRST-LINE AND ALTERNATIVES

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Preferred Regimens: Adults & Adolescents (Technician + Pharmacist)

★ 2025 First-Line Preferred Regimens (both oPEP and nPEP)

The preferred regimens for most adults and adolescents are now:

- Bictegravir (BIC) / Emtricitabine (FTC) / Tenofovir Alafenamide (TAF) S
Single-tablet, once daily (Biktarvy®)
- Dolutegravir (DTG) + (TAF or TDF) + (FTC or 3TC) — once daily

Both represent INSTIs + 2 NRTIs

Backbone approach retained from previous guidelines but with newer, better-tolerated agents.

- High barrier to resistance
- Convenient dosing (once daily, low pill burden)
- Favorable tolerability profile

Key Change : RAL Based regimens no longer preferred

Author: AD, Gross PL, Baruch A, et al. 2025 US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2025;149(1):1-11. doi:10.1017/S0950268824000047
Tanner MD, Weiss P, Carter RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV — CDC recommendations, United States, 2025. MMWR Recomm Rep. 2025;74(3):1-8.

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Alternative Regimens

When Preferred Regimens Are Not Available or Tolerated

- Raltegravir (RAL) + TDF/FTC or TAF/FTC
 - Effective but higher pill burden; remains an efficacious option if neither preferred nor alternative regimens can be prescribed
- Darunavir/ritonavir (DRV/r) + TDF/FTC or TAF/FTC (alternative boosted-PI option)

Why NOT 2-drug regimens?

- The 2-drug combination DTG/3TC is not recommended for nPEP because of caveats related to its use as initial treatment and because no data support its use for PEP
- 3-drug regimens are more likely to limit resistance emergence if infection occurs despite PEP

Author: ADL, Cynthia K. Brown, M. et al. 2020. US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2020;145(10):1171-1179. doi:10.1017/S0950268820001500
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PEP Regimen Timing and Duration

- Exposure to HIV is a medical emergency
- Time to initiative of PEP
 - Initiate as soon as possible, but no later than 72 hours after exposure
 - Do not hold therapy for pending laboratory results
- Duration of therapy
 - 28 days course
 - Course may be stopped early if source determined not to have HIV

Author: ADL, Cynthia K. Brown, M. et al. 2020. US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2020;145(10):1171-1179. doi:10.1017/S0950268820001500
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Pediatric Regimens

Children ≥2 years:

Preferred nPEP regimens for both children aged ≥2 years and adults contain two NRTIs combined with a second-generation INSTI (bictegravir or dolutegravir)

- Weight-based dosing considerations apply
- Expert consultation strongly recommended

New York State Department of Health AIDS Institute. Post-exposure prophylaxis (PEP) to prevent HIV and protect personal health. Clinical Guidelines Program. Updated December 2020. Accessed February 2021. <https://www.aidsinstitute.org/clinical-guidelines/>

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Regimen Selection Framework

Individualize Every Regimen

Consider:

- Renal/hepatic function
- Pregnancy or breastfeeding status
- Concomitant medications (DDI potential)
- Prior ARV exposure (including long-acting injectables)
- Source's treatment history and resistance profile
- Pill burden, cost, access, and adherence likelihood

If optimal regimen unavailable:

- Any 3-drug regimen suitable for initial HIV treatment may be used, provided it does not require pretesting (e.g., abacavir) and is not contraindicated

Author: ADL, Cynthia K. Brown, M. et al. 2020. US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for post-exposure prophylaxis in healthcare settings. Infect Control Hosp Epidemiol. 2020;145(10):1171-1179. doi:10.1017/S0950268820001500
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ADVERSE EFFECTS OF FIRST-LINE PEP MEDICATIONS

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Adverse Effects: BIC/FTC/TAF (Biktarvy®)

Most Common:

- Diarrhea, nausea, headache (generally mild)
- Fatigue

Drug interactions of note:

- Products containing polyvalent cations (aluminum, calcium, iron, magnesium) can bind to INSTIs and reduce absorption
- Separate administration by 2 hours

Metabolic considerations:

- Elevations in lipid levels can occur when taking TAF
- Small, reversible declines in renal function with tenofovir — the potential for adverse renal events is lower with TAF than with TDF

Musculoskeletal:

- If muscular soreness develops while taking INSTI-based PEP, creatinine kinase should be checked

United States Food and Drug Administration. Biktarvy (bictegravir/tenofovir disoproxil fumarate/emtricitabine) [prescription drug information].

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Adverse Effects: DTG-Based Regimens

- DTG-specific considerations:**
 - Insomnia, headache, depression (neuropsychiatric effects — monitor)
 - Dolutegravir decreases renal clearance of metformin by inhibiting organic cation transporters
 - Metformin dosing should be limited to 1 g/day when taken with DTG concurrently
- TDF vs. TAF comparison:**
 - TDF: Higher risk for proximal renal tubulopathy, bone mineral density loss
 - TAF: Preferred in patients with pre-existing renal impairment
- Proactive symptom management:**
 - Preemptive prescribing of antiemetics or antispasmodics for ARVs commonly associated with nausea may improve regimen continuity

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SPECIAL POPULATIONS

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Pregnancy

- ★ Pregnancy is NOT a contraindication to PEP**
- Pregnant or breastfeeding women should have rapid access to nPEP when indicated
 - Risks of ARV exposure must be weighed against risks of maternal HIV acquisition and potential perinatal HIV transmission
- A pregnancy test should be performed in all women of childbearing potential at initial evaluation

Pharmacokinetic changes in pregnancy may lead to lower plasma levels of certain ARVs and may require increased doses or more frequent dosing

- Avoid Cobicistat-boosted atazanavir, darunavir, and elvitegravir in pregnancy due to lack of safety/PK data or inferior virologic efficacy
- Refer to HHS Perinatal Guidelines for safety/toxicity data by agent

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Breastfeeding

- Providing nPEP to women who are breastfeeding and are at substantial risk for HIV acquisition reduces the risk for HIV transmission to the breastfeeding infant
- Counsel on risk of HIV transmission through breast milk if acute infection occurs
- Options
 - Continue with close monitoring
 - Pump and store until HIV excluded
 - Stop breastfeeding
- Shared decision-making approach — quality counseling supports shared decision-making regarding infant feeding during an nPEP course
- Consult NCCC PELine or Perinatal HIV Line (844-ASK-NCCC or 844-275-6222)

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Drug-Drug Interactions

- Before Dispensing**
 - Verify the Full Medication List
 - OTC medications
 - Vitamins
 - Minerals
 - Herbal remedies
- Resources**
 - HIV Drug Interactions – University of Liverpool - <https://www.hiv-druginteractions.org>

Concomitant Drug	Interaction	Action
Rifampin/Rifabutin	Induces CYP3A4/UGT1A1 + ↓ BIC/DTG levels	Contraindicated
Metformin	DTG inhibits renal OCT + ↑ metformin exposure	Cap at 1g/day
Antacids/Multivitamins	Chelation of INSTIs	Separate by 2 hours
PPis	↑ absorption of acid-dependent ARVs (e.g., rilpivirine)	Avoid in rilpivirine-based regimens
Anticonvulsants	May reduce INSTI exposure	Avoid / consult

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Renal Impairment

Tenofovir Formulation Matters:

- TDF — associated with proximal renal tubulopathy; dose adjustment required for CrCl <50 mL/min
- TAF — preferred in renal impairment; less nephrotoxic; no dose adjustment needed until CrCl <15 mL/min

- Exposed persons with impaired renal function may require dose adjustments and additional creatinine monitoring while completing the 28-day PEP course
- Short duration of PEP limits overall nephrotoxicity risk
 - Small declines in renal function with daily tenofovir reverse upon cessation, and the incidence of serious renal events is very low because of PEP's short-term duration
- HBV Co-infection: Tenofovir + FTC or 3TC-containing regimens preferred (dual activity); monitor for hepatic flare on discontinuation

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Persons Previously on Long-Acting Injectable ARVs

- A New Consideration in 2025 Guidelines:
 - Suboptimal levels of cabotegravir (CAB) from prior long-acting injectable PrEP could last up to 3 years in men and 4 years in women
 - INSTIs might not be preferred
 - When the source has detectable viremia while on long-acting injectable ART
 - When the exposed patient has remote history of long-acting injectable ARV use
- For persons with long-acting injectable PrEP ARV exposure during the past 12 months, a diagnostic HIV NAT is recommended at initial medical evaluation, in addition to an Ag/Ab HIV test

Expert consultation strongly recommended in these cases

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LABORATORY TESTING FOLLOW-UP & PREP TRANSITION

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Baseline and Follow-Up Testing

At Initiation (do not delay PEP for results):

- HIV Ag/Ab combination test ± rapid (POC) test
- Serum creatinine + eGFR
- ALT and AST
- HBV panel (HBsAg, anti-HBs, anti-HBc)
- Pregnancy test (women of childbearing potential)
- STI screening (gonorrhea, chlamydia, syphilis) as clinically indicated

Follow-up testing schedule (2025 update — streamlined):

24 hours (phone/in-person)

Confirm access to meds, assess tolerability

4-6 weeks post-exposure

HIV Ag/Ab + HIV NAT*

12 weeks post-exposure

HIV Ag/Ab + HIV NAT (final)

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KEY TAKEAWAYS

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The PEP-to-PrEP Bridge

Every PEP Encounter is a PrEP Opportunity

- All persons prescribed nPEP should be informed that PrEP can reduce their risk for acquiring HIV if they will have repeat or continuing exposure after the end of the nPEP course
- Immediate transition from nPEP to PrEP — including HIV testing at completion of the nPEP regimen with a prompt transition to a recommended PrEP regimen
 - may be beneficial for persons with anticipated repeat or ongoing potential HIV exposures
- PrEP guidelines do not recommend a gap between nPEP conclusion and PrEP initiation
- Counsel about possibility of false-negative HIV test if starting PrEP before 12-week follow-up test

PrEP Regimen Options:

- Daily oral: TDF/FTC or TAF/FTC
- Event-driven (2-1-1): TDF/FTC for sexual exposures
- Long-acting injectable: Cabotegravir every 2 months

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oPEP What's New in 2025?

	2013 Guideline	2025 Update
Preferred regimens	RAL or LPV/r-based	BIC/FTC/TAF or DTG + TDF/TAF + FTC/3TC
Undetectable viral load	PEP recommended	Shared clinical decision-making — may forego or discontinue PEP early when source has undetectable VL
Routine lab monitoring	Follow-up labs for toxicity recommended	Elimination of routine labs for ARV toxicity — only if baseline abnormal or clinical indication
Follow-up testing window	Up to 6 months	Final HIV test at 12 weeks (99% detectable within 44 days)
HCP on PrEP at exposure	Not addressed	New guidance for HCP already on PrEP at time of occupational exposure
Long-acting injectable ARVs	Not addressed	Guidance for HCP with prior CAB-based PrEP in past 12 months
Shared decision-making	Provider-directed	HCP actively included in PEP initiation decision

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What's New in 2025? - nPEP

	2013 Guideline	2025 Update
Preferred regimens	RAL or boosted PI-based	BIC/FTC/TAF or DTG • (TAF or TDF) • (FTC or 3TC)
Time to initiation	≤72 hours	Increased emphasis on optimal administration within first 24 hours
nPEP indications	Limited scenarios	Expanded discussion of persons with HIV on viral suppression, persons on PrEP, sexual assault survivors
Follow-up testing	Up to 6 months	Ag/Ab • NAT at 4–6 weeks and 12 weeks — routine CUA/AST follow-up no longer necessary unless baseline abnormal
HIV testing modality	Ag/Ab test	Ag/Ab • HIV NAT at follow-up; NAT at baseline for prior long-acting injectable PrEP users
PEP-to-PrEP transition	Mentioned	Greater emphasis transition plan required for all with ongoing risk; immediate transition now an option
Sexual assault	Mentioned	Testing updated to align with 2021 CDC STI Treatment Guidelines

Tanner MS, Mahe R, Carter RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV — CDC recommendations, United States, 2025. *Morbidity and Mortality Weekly Report*. 2025;74(3):48.

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Phone A Friend – Additional Resources

- National Clinician Consultation Center
 - Warm line - 844-ASK-NCCC or 844-275-6222
 - Clinical Resource Library
 - Clinical Training
 - <https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/>
- HIV Drug Interactions – University of Liverpool - <https://www.hiv-druginteractions.org/>
- Antiretroviral Pregnancy Registry at <http://www.apregistry.com>; telephone: 800-258-4263; fax: 800-800-1052; email: sm_apr@apregistry.com
- FDA (for reporting unusual or severe toxicity to antiretroviral agents): <http://www.fda.gov/medwatch>; telephone: 800-332-1088
- The CDC's Cases of Public Health Importance (COPI) coordinator (for reporting HIV infections in HCP and failures of PEP) at telephone number 404-639-2050.
- HIV/AIDS Treatment Information Service at <http://aidsinfo.nih.gov/>

Related Clinical Resources

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- CDC. *Diagnoses of HIV infection in the United States and dependent areas, 2022*. HIV Surveillance Report 2024;35.

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Questions?

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Needle-stick to Next Steps: Occupational and Nonoccupational HIV Postexposure Prophylaxis Guideline Updates

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Thank you!

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