



Indiana
Department
of
Health

**POST-EXPOSURE
PROPHYLAXIS
HIV ANTI-RETROVIRAL
MEDICATIONS**

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OUR MISSION:

**To promote, protect, and improve
the health and safety of all
Hoosiers.**

OUR VISION:

**Every Hoosier reaches optimal
health regardless of where they live,
learn, work, or play.**



What is PEP?

Post-Exposure Prophylaxis: taking anti-retroviral medications following a true or potential exposure to HIV to prevent being infected.

- **MUST BE STARTED WITHIN 72 HOURS OF EXPOSURE. Every hour counts!**
- HIV status must be tested prior to starting meds.
 - If rapid HIV test is not available, follow facility policy to test for HIV and start the medications at time of exam. Continue regimen with negative results. If patient test is positive, contact the patient to stop the medications and refer them for immediate follow-up care.

Taken 1-2 times daily (depending on medications prescribed) for 28 days.

- Full 28-day prescription must be completed for highest rate of efficacy



CDC Recommended Treatment

Medications, dosing, frequency, and duration

	Drug 1	Drug 2	Drug 3	Duration
OPTION 1	Tenofovir DF/emtricitabine (TDF/FTC) 300/200 mg (Truvada®), 1 tablet PO daily	+ dolutegravir (Tivicay®)* 50 mg, 1 tablet PO daily	-	28 days**
OPTION 2	TDF/FTC 300/200 mg (Truvada®) 1 tablet PO daily	+ raltegravir (Isentress®) 400 mg, 1 tablet PO BID	-	28 days
ALTERNATIVE	TDF/FTC 300/200 mg (Truvada®) 1 tablet once daily	+ darunavir (Prezista®) 800 mg, 1 tablet daily	+ ritonavir 100 mg, 1 tablet daily	28 days

* If the patient is a woman who may conceive while on the medication, or is in the early stages of pregnancy, do not prescribe dolutegravir.

** If the pharmacist will not dispense less than a 30-day supply of nPEP medications (because of cost to the pharmacist of removing tablets from a 30-day bottle), then a prescription for a 30-day supply should be given and patients should be instructed to take medications only for 28 days.

Source: https://aidsetc.org/sites/default/files/resources_files/



Adverse Reactions

Common:

- Abdominal pain
- Nausea/Vomiting
- Headache
- Diarrhea
- Fatigue

Rare:

- Hepatic toxicity
- Decreased renal function

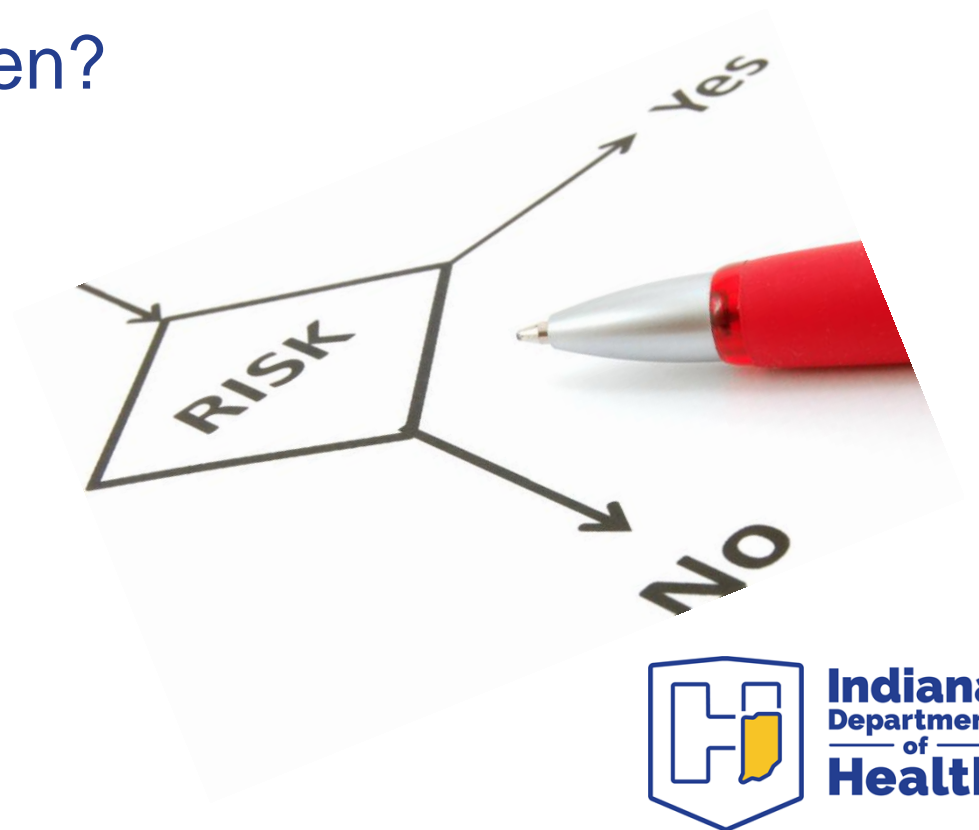
*Patients should be educated on benefits and side effects of taking PEP to make an informed decision.



Risk Assessment

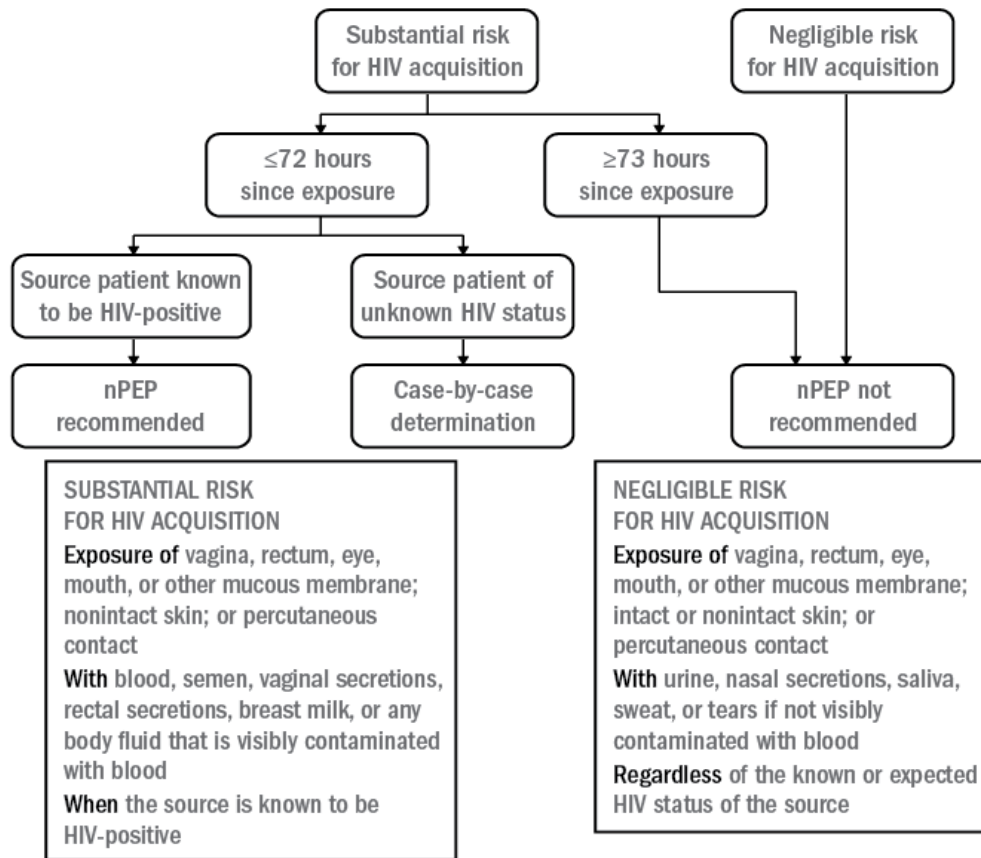
Use your clinical judgment to determine risk of exposure and benefit of treatment

- What went where when?
- Risk behaviors
- Patient adherence



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Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposure



Source: Centers for Disease Control and Prevention¹

HIV Risk Behaviors

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The risk of getting HIV varies widely depending on the type of exposure or behavior (such as sharing needles or having sex without a condom). Some exposures to HIV carry a much higher risk of transmission than other exposures. For some exposures, while transmission is biologically possible, the risk is so low that it is not possible to put a precise number on it. But risks do add up over time. Even relatively small risks can add up over time and lead to a high lifetime risk of getting HIV. In other words, there may be a relatively small chance of acquiring HIV when engaging in a risk behavior with an infected partner only once; but, if repeated many times, the overall likelihood of becoming infected after repeated exposures is actually much higher.

The table below lists the risk of transmission per 10,000 exposures for various types of exposures.

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23
Sexual	
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Other[^]	
Biting	Negligible
Spitting	Negligible
Throwing Body Fluids (Including Semen or Saliva)	Negligible
Sharing Sex Toys	Negligible

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[^] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Source:

- Patel P, Borkowf CB, Brooks JT, et al. Estimating per-act HIV transmission risk: a systematic review. *AIDS*. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. *Am J Forensic Med Pathol* 1999;20(3):232-239.



Clinician-to-Clinician Assistance

HRSA's AIDS Education and Training Center (AETC) Program supports national HIV priorities by building clinician and care team capacity and expertise along the HIV care continuum.



<https://aidsetc.org/>

AETC National Clinician Consultation Center's (NCCC's) Post-Exposure Prophylaxis Hotline (PEPline)

- 888-HIV-4911 (888-448-4911)
- 9:00 AM - 9:00 PM ET, 7 days/week

The AETC NCCC PEPline works with providers to:

- Assess the risk of exposure
- Determine the appropriateness of prescribing PEP
- Select the best PEP regimen
- Provide recommendations for follow-up testing



What Patients Need to Know

- Risk of exposure and what it means for them
 - High
 - Moderate
 - Low/Negligible
- Med Ed: Purpose/Benefit/Side effects
- Course of treatment and importance of adherence
- Not 100% effective even if taken as prescribed for the full 28 days
 - Non-adherence to treatment plan will decrease efficacy.
- Ultimately it is your patient's choice--make sure they can make a fully informed decision

5-Day Supply

Challenges getting the 5-day supply

- Inpatient pharmacy supply: opening and repackaging supply to protect the expiration dates (per regulations)
- Outpatient pharmacy partnership
 - Talk to your pharmacy team to create a system that works for this patient population

23-Day Supply

Outpatient/retail pharmacy ordering

- Work with your facility's outpatient pharmacy or a nearby retail pharmacy (24-hour preferred) to have 1-2 PEP supplies in stock.
 - Medications are good for up to 2 years and can be exchanged with the manufacturer for a new supply upon expiration
- Understand urgency for ordering purposes when PEP supply is not available
- Partner with the pharmacy to create an efficient process that works for everyone to achieve optimal outcomes

Facility Reimbursement

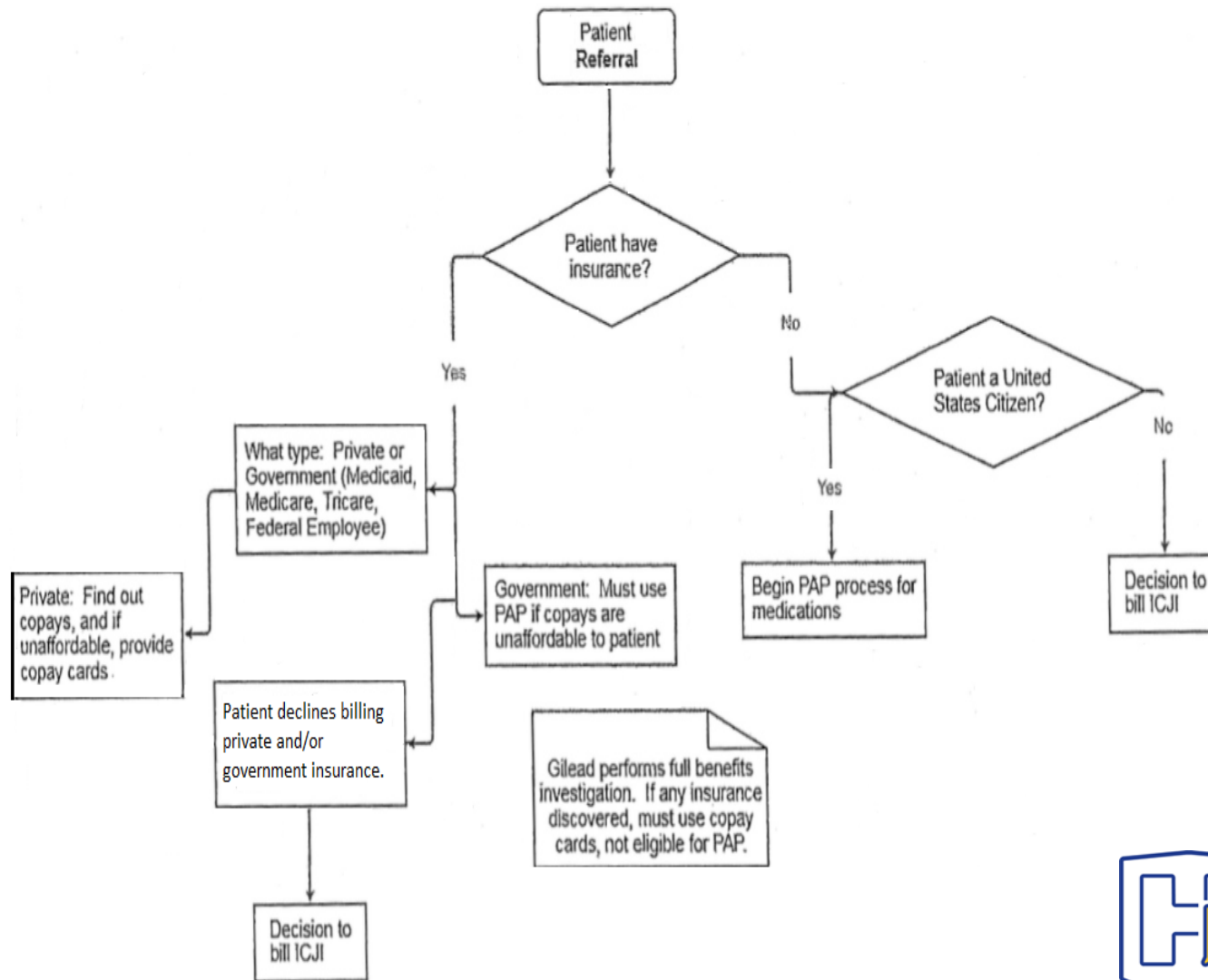
What are your options?

- Insurance/Co-pay cards
- Pharmaceutical Manufacturer Patient Assistance Program (PAP)
- ICJI



Decision Tree

What is working for other facilities



POST-EXPOSURE PROPHYLAXIS (PEP) MEDICATION ASSISTANCE PROGRAMS

MANUFACTURER-BASED PROGRAMS:

1. **Gilead's "Advancing Access®": FTC/TDF (Truvada®)**
200/300mg once daily: 1-800-226-2056 https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf
 - a. Provider/Patient Advocate (e.g., RN, MA, pharmacist, SW/case manager) must first fax enrollment form: 1-800-216-6857
 - b. Call Advancing Access® program (Option 1) 30 minutes after faxing form: **Monday – Friday, 8am-8pm ET**
 - c. Patient will be screened over the phone—Immediate medication access (voucher) number is given if patient qualifies
 - d. Patient picks up medication from any pharmacy with voucher
2. **Merck's SUPPORT™: Raltegravir (Isentress®)**
400mg twice daily: 1-800-727-5400
 - a. Patient and provider complete application together: https://www.merckhelps.com/docs/MPAP_Enrollment_Form_English.pdf
 - b. Write "Urgent" or "PEP" across top of form, & fax to: 1-800-528-2551
 - c. **If form is submitted by 2:30 pm ET, medication will be delivered to patient's home address by 1:30 pm ET next day**
3. **ViiV: Dolutegravir (Tivicay®)** 50mg once daily: 1-844-588-3288
 - a. Patient Advocate calls or enrolls online
 - i. Access Coordinator between **8am-8pm ET** to complete patient enrollment process & receive voucher number; **OR**
 - ii. Use web-based enrollment option (available 24/7): <https://www.viivconnect.com/portal/>
 - b. 30-day supply available at no charge for patients who qualify (cannot have Medicare Part D coverage; must earn less than 500% FPL; must be U.S. resident)
 - c. ViiV activates voucher: patient then takes voucher number to any pharmacy for same-day pick up

This information is subject to change - contact programs directly to verify current enrollment process. April 2019.

Source: https://aidsetc.org/sites/default/files/resources_files/Updated%20nPEP-med%20patient%20assist%20Postcard.pdf

Questions & Assistance

Indiana Department of Health

Office of Women's Health

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Resources

Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. Sexual Assault and Abuse and STDs, 2017. <https://www.cdc.gov/std/tg2015/sexualassault.htm#riskHIV>

Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. Post-Exposure Prophylaxis (PEP), 2016. <https://www.cdc.gov/hiv/risk/pep/>

Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. Factors Increasing the Risk of Acquiring or Transmitting HIV, 2015. <https://www.cdc.gov/hiv/risk/estimates/riskfactors.html>

AETC National Coordinating Resource Center. Non-Occupational Post-Exposure Prophylaxis (nPEP) Toolkit, 2018. https://aidsetc.org/sites/default/files/resources_files

