

Providing nPEP and PrEP in a Community Health Center

nPEP: non occupational post exposure prophylaxis
PrEP: pre exposure prophylaxis

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Providing nPEP and PrEP in a Community Health Center

Objectives

1. **Why?** Review efficacy and safety data for nPEP/PrEP
2. **Who, When?** Review guidelines for nPEP and PrEP
3. **How?** Understand evaluation and monitoring when prescribing nPEP and PrEP
4. **How?** List the challenges for a community health center to apply the guidelines in the real world and consider solutions

CalLEN ▼ LORDE
COMMUNITY HEALTH CENTER

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Agenda: nPEP and PrEP

Controlling the epidemic

nPEP and PrEP, a continuum of care

nPEP

PrEP

Evidence for PEP:

Animal transmission models

Perinatal clinical trials

Occupational PEP

Observational Studies

Considered Possible Negative Consequences of nPEP

Impact on Risk Reduction

Side effects

Selection of resistant virus

Cost

Cost effectiveness

Access

nPEP Evaluation

Clinical Assessment and Plan

Substantial risk?

Timing?

Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan

Insurance?

Ability to pay?

Immigration status?



Table 1: Consideration of nPEP According to the Type of Risk Exposure^a

nPEP recommended	penile-anal sex penile-vaginal sex needle sharing
nPEP considered	oral-vaginal sex oral-anal sex penile-oral sex
	factors that increase risk should be considered
nPEP not recommended	oral-oral contact human bites

(edited from) NYSDOH AIDS Institute

www.hivguidelines.org

New York State DOHMH Clinician PEP-Line
(866) 637-2342
24 hours/7 days per week

UCSF PEP-line
(888) 448-4911
9:00 AM – 2:00 AM EST/7 days per week

NYSDOH AIDS Institute

nPEP

July 2013 Updates

www.hivguidelines.org

- ♦ **Consider HIV VL test in source patient**
- ♦ **Baseline STI Screening**
- ♦ **Post exposure HIV test at 4 & 12 weeks**
- ♦ **Consideration for PrEP**
- ♦ **Choice of nPEP Rx**

(including dolutegravir from October 2014)

NDC 0006-0227-61
Isentress[®]
(raltegravir) tablets
400 mg

NDC 61958-0701-1
Truvada[®]
(emtricitabine and tenofovir
disoproxil fumarate)
Tablets



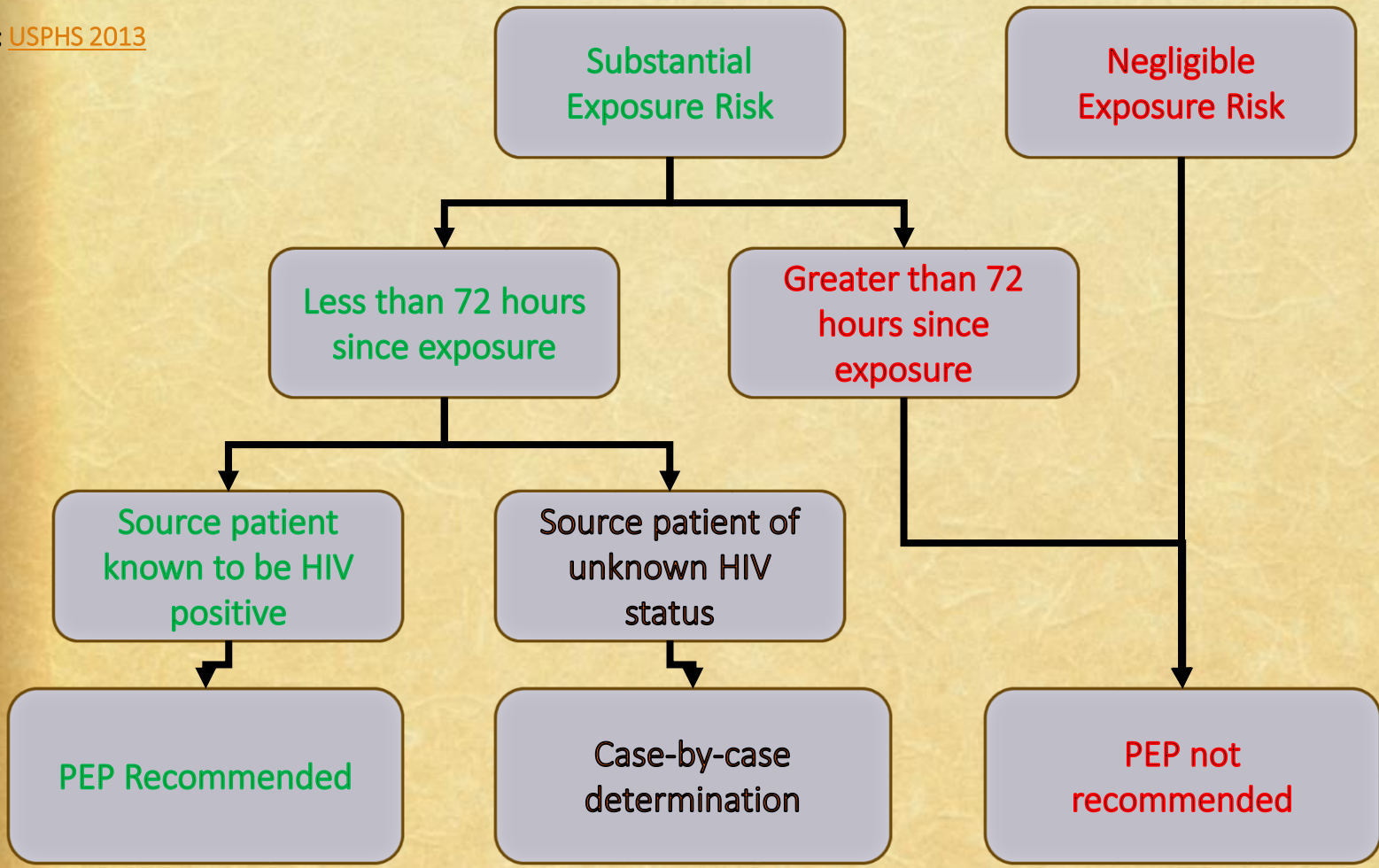


PRESCRIBING INFORMATION

NDC 49702-228-13 Rx Only
Tivicay
(dolutegravir)
Tablets
50 mg
Each film-coated tablet contains dolutegravir sodium equivalent to 50 mg of dolutegravir.
30 Tablets

Figure. Algorithm for evaluation and treatment of possible HIV exposures.

DHHS 2005; USPHS 2013



- Substantial Risk for HIV Exposure**
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact
 - With... blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
 - When... source is known to be HIV-infected

- Negligible Risk for HIV Exposure**
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, intact or non-intact skin, or percutaneous contact
 - With... urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
 - Regardless... of the known or suspected HIV status of the source

What tests to do & when?



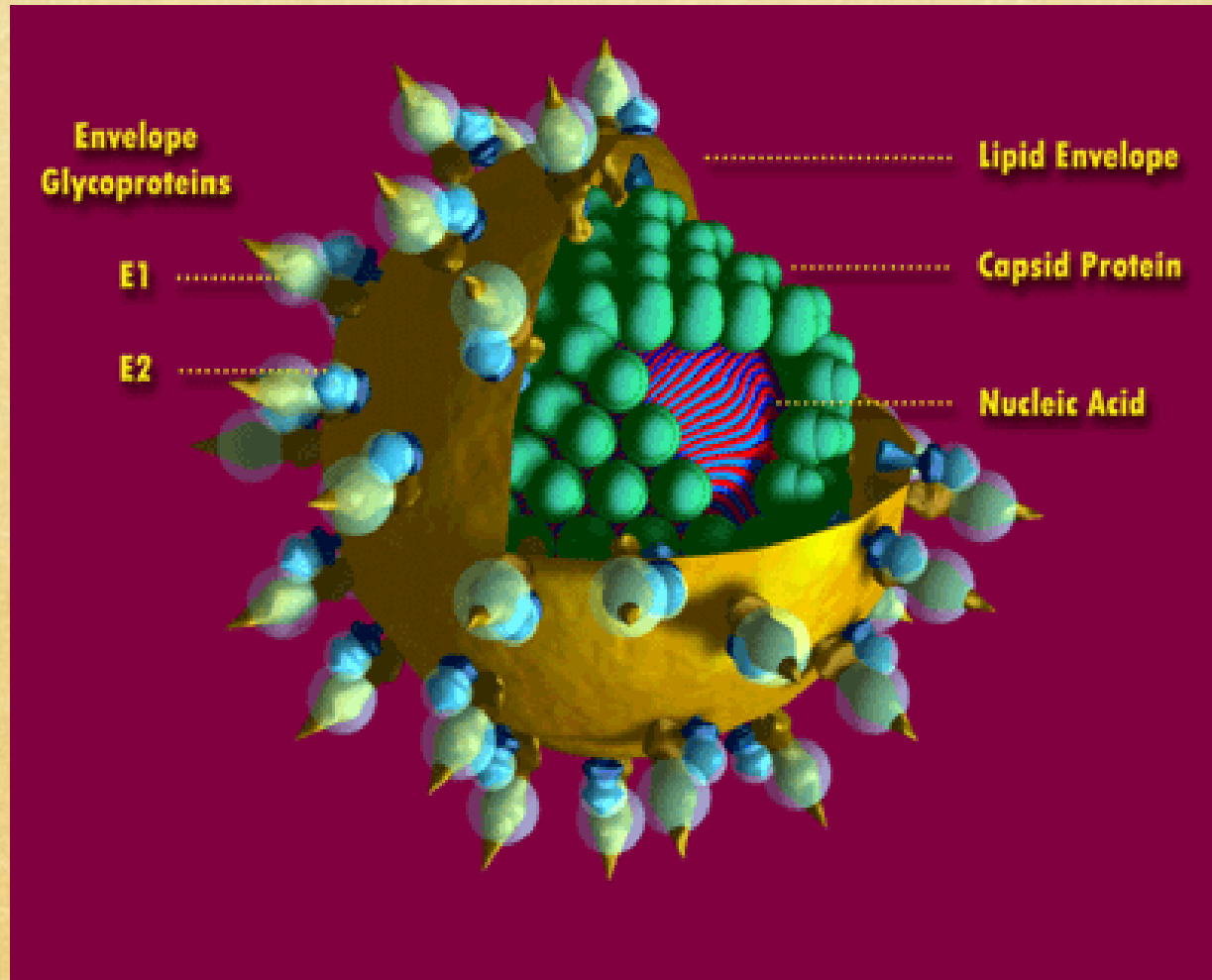
Monitoring Recommendations After Initiation of PEP Regimens Following Non-occupational Exposures

Week	Baseline	1	2	3	4	12
Clinic Visit	X	X (or by phone)	X (or by phone)	X (or by phone)	X	
Pregnancy Test	X					
Serum liver enzymes, BUN, creatinine, CBC	X		X		X	
HIV test - Recommended even if PEP is declined	X				X	X
STI Screening - Recommended even if PEP is declined	X		X			
Hepatitis B and C						

SOURCE: HIV CLINICAL RESOURCE

([HTTP://WWW.HIVGUIDELINES.ORG/CLINICAL-GUIDELINES/POST-EXPOSURE-PROPHYLAXIS/HIV-PROPHYLAXIS-FOLLOWING-NON-OCCUPATIONAL-EXPOSURE/](http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/))

Remember to consider Hep C



Cindy

Victor

Shanelle

Roberto



Cindy is a 33 year old woman, “I’m really worried about HIV – I had sex 30 hours ago with someone new”

Victor




Shanelle




Roberto



Unprotected receptive oral sex with new male partner, with ejaculation



Partner unknown HIV status and he declines getting an HIV test





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Unprotected receptive oral sex with new male partner, with ejaculation			
Partner unknown HIV status and he declines getting an HIV test			
Not suitable for nPEP, STD testing including HIV, family planning. More information needed regarding PrEP			

Cindy is a 33 year old woman, “I’m really worried about HIV – I had sex 30 hours ago with someone new”	Victor is a 44 year old gay man reports episode 4 days ago that “I’d like an STD check up because of”	Shanelle	Roberto
Unprotected receptive oral sex with new male partner, with ejaculation	When high, condom-less insertive & receptive anal sex with ejaculation		
Partner unknown HIV status and he declines getting an HIV test	Multiple partners, unknown status although sero-sorts on line - Rectal GC last month		
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nPEP Evaluation

Clinical Assessment and Plan

Substantial risk?

Timing?

Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan

Insurance?

Ability to pay?

Immigration status?



nPEP Flow sheet(s)

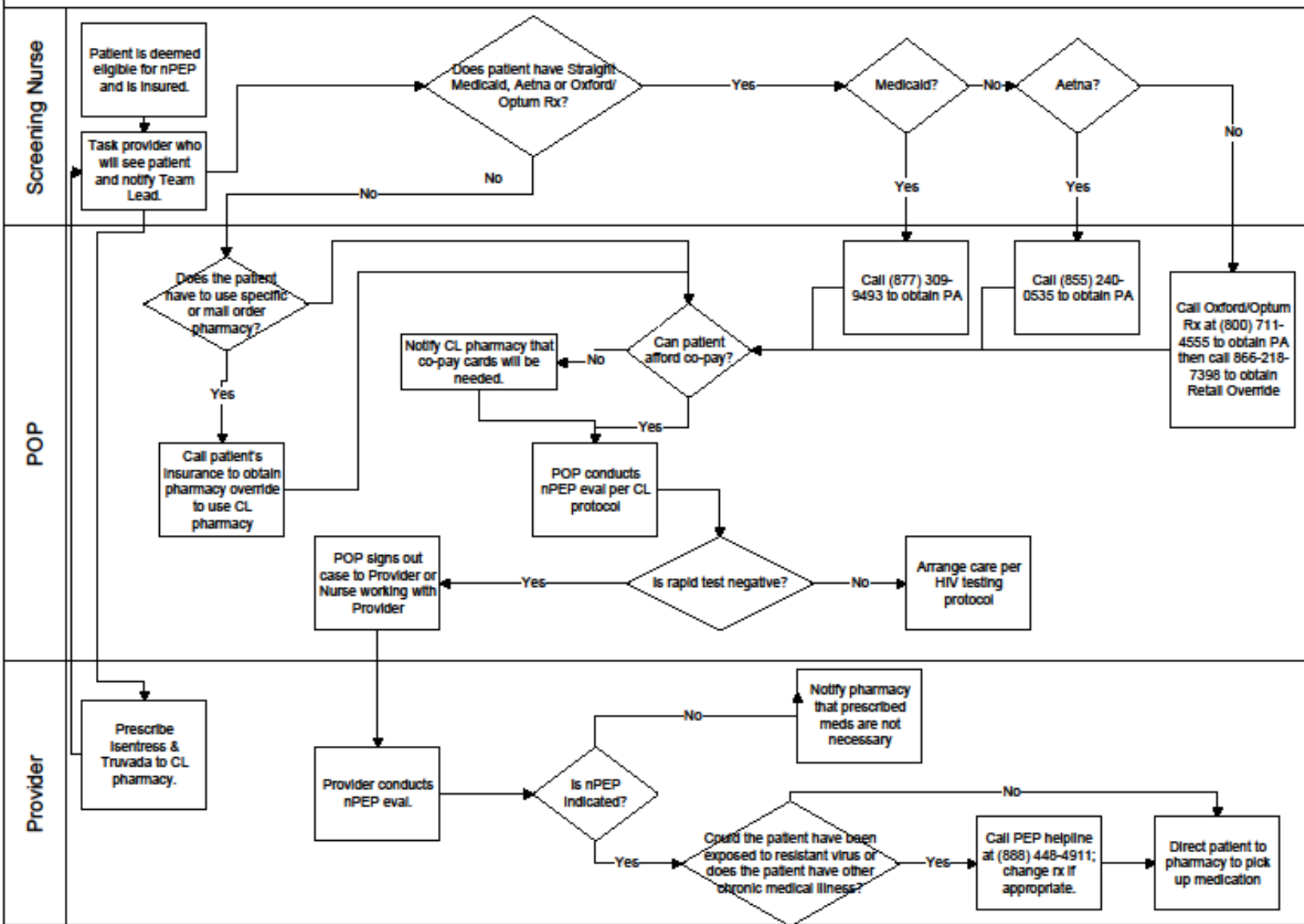
PPEP (private insurance)

PAP-PEP (pharmacy assistance program)

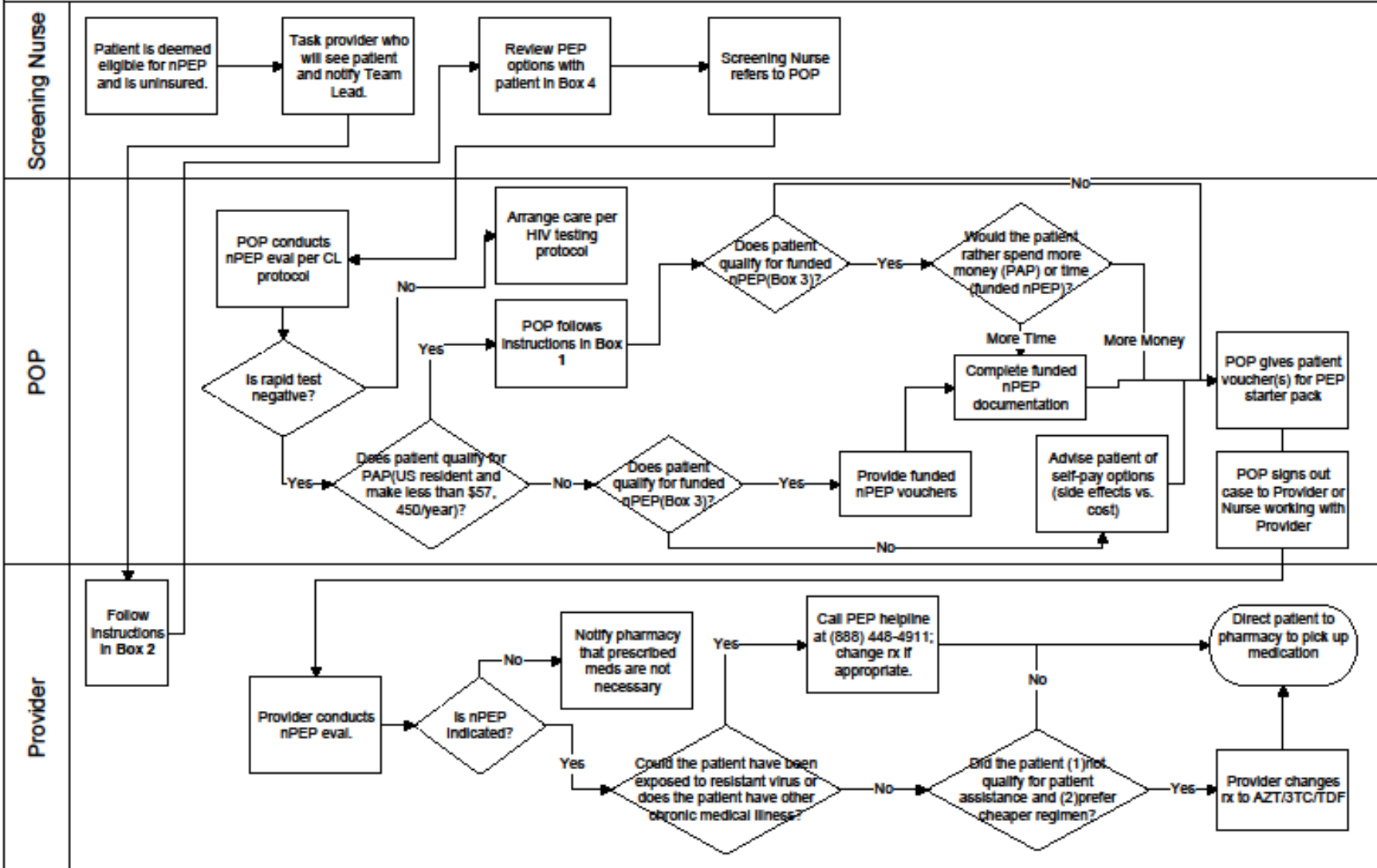
SPEP (self pay)

FPEP (funded PEP)

nPEP – Insured Patient



nPEP – Uninsured or Underinsured Patient



Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (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 www.isentress.com
Insured, but does not use insurance	<ul style="list-style-type: none">• 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) http://hab.hrsa.gov/patientassistance/index.html 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 regimen chosen. <i>Please see specific application process on next page for Gilead and Merck.</i>

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))

Patient Assistance Programs

Gilead Patient Assistance

1. Fax a letter of medical necessity to 1-800-226-2056.

Include:

- Patient's name
- Therapy needed
- Date of exposure
- Provider's signature

2. 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
- Have this information available:
 - Name
 - Address
 - Phone number
 - Date of birth
 - Social security number
 - Number of people claimed as dependents
 - Household income
 - Any insurance coverage
 - Provider name
 - Provider address
 - Provider phone number
- Will take 5-10 minutes
- Hours: Monday - Friday 9am-8pm EST

3. 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.

4. **Co-payment Assistance:** Call 1-877-505-6986. Hours: Monday - Friday 8am– 8pm EST. Patient is given an authorization number to present with the prescription and other insurance at the pharmacy.

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([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))

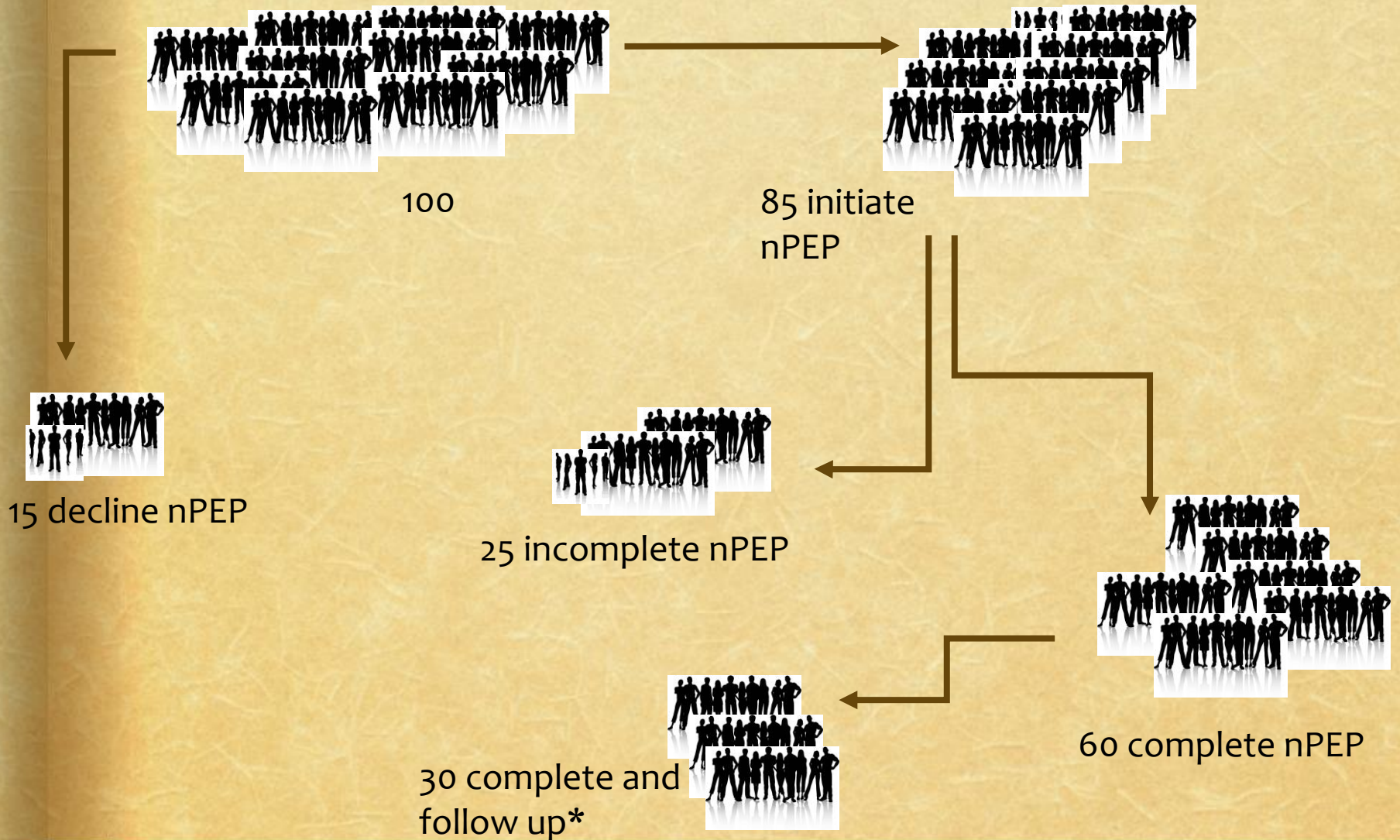
Patient Assistance Programs

1. **Merck Patient Assistance Program**
2. Locate form at www.needymeds.org
 - Under A-Z, look for Isentress (Raltegravir). (www.needymeds.org/papforms/isentr1196.pdf)
 - Support enrollment form
 - Print and fill out
 - **Indicate prescribing PEP**- this will expedite processing.
 - Fax to 1-866-410-1913. You may send fax any time. Hours of operation: 6am - 3pm PST Monday - Friday.
3. Call 1-800-850-3430 1-2 hours after sending fax.
4. 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)
5. **Co-payment Assistance:** Call 1-855-834-3467 or www.isentress.com
 - For online application and coupon redemption
 - For presentation with the prescription and insurance coverage at the pharmacy.

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))

PEP Cascade



PrEP

Why PrEP?

Evidence

Guidelines

Applying the guidelines

Strategy for epidemic control:

Patient Care & Public Health - nPEP and PrEP



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Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

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THE LANCET Infectious Diseases

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Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study

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Evidence for PrEP

Study Name	Population	N	Results
Partners PrEP	Discordant Heterosexual couples	4,758	TDF: 67% efficacy FTC/TDF: 75% efficacy 90% if detectable drug
TDF2 Study	Heterosexual Men and Women	1,219	FTC/TDF: 62% efficacy 85% if detectable drug
iPrEx	MSM	2,499	FTC/TDF: 44% efficacy 91% if detectable drug
Thai IVDU	IVDU	2,413	TDF: 49% efficacy 74% if detectable drug

CDC recommend PrEP for individuals

in an ongoing relationship with an HIV-infected partner

not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and who is:

a gay or bisexual man who has had sex without a condom or been diagnosed with a sexually transmitted infection within the past six months.

a heterosexual man or woman who does not regularly use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status) or whose partners are from communities with high rates of HIV infection.

has injected illicit drugs within the past six months and has shared equipment or been in drug treatment within the past six months.



Initiation and follow up of PrEP patients

Pre-Prescription Visit:

- Discuss PrEP use; clarify misconceptions
- Perform following laboratory tests:
 - HIV test (see Table 6 for guidance on what type of test to use)
 - Metabolic panel
 - Urinalysis
 - Hepatitis A, B, and C serology
 - STI screening
 - Pregnancy test

After confirmation of negative HIV test:
Prescribe 30-day supply of PrEP
 Follow up in 2 weeks to assess side effects (in person or by phone)

Adherence and commitment should be assessed at each visit. Schedule visits every 30 days for patients who report poor adherence or intermittent use.

30-day visit:

Assess:

- Side effects
- Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
- Discuss risk reduction and provide condoms

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and follow-up assessments, then 90-day schedule can begin

3-month visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

6-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- Discuss risk reduction and provide condoms
- Pregnancy test

9-month visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

12-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- HCV serology for MSM, IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms
- Pregnancy test
- Urinalysis

Discussions with the patient:

Educate about the following:	Talking Points:
How PrEP works	Explain how PrEP works in language easy to understand Explain how PrEP works as part of a comprehensive, prevention plan
Limitations of PrEP	Efficacy dependent on adherence Reduces but does not eliminate HIV risk Does not protect against other stds
PrEP Use	Dosing and need for daily adherence # of sequential doses to achieve protective effect Reinforcement of condom use in period following missed doses
Common side effects	Headache, abdominal pain, weight loss. side effects improve after first month Standard measures (anti-diarrheal, anti-gas, anti-emetics) should be used to alleviate symptoms

Contraindications:

HIV infection

Renal compromise

Considerations:

Co-administered nephrotoxic drugs

Hepatitis B infection

Pregnancy or desire for pregnancy

Adolescent

Bone health

Maria is 35 year old heterosexual HIV-woman, her husband is HIV+ and is struggling to get his VL to undetectable

Lindsey is a 26 year old female sex worker

Usually use male condoms for vaginal sex, not for oral sex. She has recurrent oral herpes.

She always tried to use condoms with clients.

She is worried about getting HIV as she knows risk is higher when his VL is elevated.



Maria is 35 year old heterosexual HIV-woman, her husband is HIV+ and is struggling to get his VL to undetectable

Victor is a 44 year old gay man reports episode 4 days ago that “I’d like an STD check up because of”

Lindsey is a 26 year old female sex worker

Roberto is a 25 year old gay man, “bottomed” last night & “the condom broke”

Usually use male condoms for vaginal sex, not for oral sex. She has recurrent oral herpes.

When high, condom-less insertive & receptive anal sex with ejaculation

She always tried to use condoms with clients.

Receptive anal sex with new partner of unknown HIV status, pre-cum but no ejaculation

She is worried about getting HIV as she knows risk is higher when his VL is elevated.

Multiple partners, unknown status although sero-sorts on line - Rectal GC

First time he has had anal sex, single and very fearful of getting HIV



Resources:

Accessing Truvada

	Gilead PrEP Medication Assistance Program
Eligibility Criteria	US resident, uninsured or no drug coverage, HIV-negative, low income
Drug Fulfillment	Covance Specialty Pharmacy, labeled for individual patient use and shipped to Prescriber
Recertification	6 months, with 90 day status check

<http://www.truvada.com/starting-truvada>

Resources

nPEP

New York State DOHMH Clinician PEP-Line

(866) 637-2342

24 hours/7 days per week

UCSF PEP-line

(888) 448-4911

9:00 AM – 2:00 AM EST/7 days per week

PrEP

HIVguidelines.org

CDC.gov/hiv/pdf/PrEPProviderSupplement2014.pdf

pmeacher@callen-lorde.org