



**SOUTH *TO SOUTH*  
LEARNING NETWORK**

*Reimagining HIV Prevention*

# Standard Operating Procedure for Injectable Lenacapavir as Pre-exposure Prophylaxis



The intent of this document is to provide an adaptable standard operating procedure (SOP) to support the development and adoption of national SOPs that align with World Health Organization (WHO) recommendations and guidance on injectable lenacapavir (LEN) as pre-exposure prophylaxis (PrEP).

**Updated August 2025**



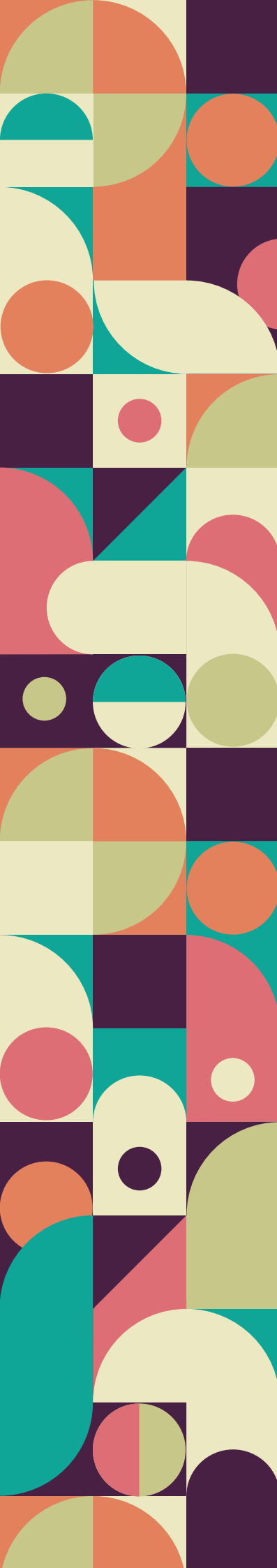
## Acknowledgements

This document was developed by the South-South HIV Prevention Learning Network-Insight 2 Implementation with input and review by the Clinton Health Access Initiative, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Wits RHI.

If you have any queries related to this SOP, reach out to us at [info.i2i@genesis-analytics.com](mailto:info.i2i@genesis-analytics.com).

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Designed as a template, this tool offers language and points for consideration for use by national policymakers during the creation or adaptation of national SOPs for LEN as PrEP.

This content could also be adapted for national guidelines on LEN PrEP or as a policy addendum where more intensive guideline development processes could delay LEN PrEP introduction and scale.

The document includes prompts for national-level consideration during the SOP adaptation process. Areas specifically requiring national updates are indicated in **red font**; sections for additional consideration by policymakers, shown in **green boxes**, are informed by regulatory bodies, available product information, and country-level insights. Once a decision has been made about the considerations in green boxes, text can be added, and the green boxes can be removed.

#### The content of this document was sourced largely from:

- ↓ Guidelines on Lenacapavir for HIV Prevention and Testing Strategies for Long-acting Injectable PrEP from WHO (July 2025)
  - ↓ The WHO and Jhpiego Provider Training Toolkit on Use of Oral and Long-Acting HIV Pre-Exposure Prophylaxis (PrEP) (July 2025)
  - ↓ United States Food and Drug Administration Yeztugo Label (June 2025)
  - ↓ Provider Module for Oral and Long-acting PrEP from WHO (July 2024)
  - ↓ Updated Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention from WHO (July 2022)
  - ↓ Consolidated Guidelines on HIV Viral Hepatitis and STI Prevention, Diagnosis, Treatment, and Care for Key Populations from WHO (July 2022)
  - ↓ Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach from WHO (July 2021)
  - ↓ Updated Recommendations on HIV Prevention, Infant Diagnosis, Antiretroviral Initiation and Monitoring Guidelines from WHO (March 2021)
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# LIST OF ACRONYMS

AGYW	Adolescent girls and young women
AHI	Acute HIV infection
ARV	Antiretroviral
GBV	Gender-based violence
HIVST	HIV self-testing
IPV	Intimate partner violence
ISR	Injection site reactions
LEN	Injectable lenacapavir
LIVES	Listen, Inquire, Validate, Enhance Safety and Support
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
SOC	Standard of care
STI	Sexually transmitted infections
VMMC	Voluntary medical male circumcision
WHO	World Health Organization





# OVERVIEW OF PRE-EXPOSURE PROPHYLAXIS

Pre-exposure prophylaxis (PrEP) is the preemptive use of antiretroviral (ARV) drugs by people who do not have HIV to reduce the probability of HIV acquisition. The level of effectiveness provided by PrEP is strongly correlated with effective use, meaning it is important for clients to use PrEP methods as prescribed during periods when they may be at increased likelihood of acquiring HIV. Current PrEP methods recommended by the World Health Organization (WHO) do not prevent pregnancy or sexually transmitted infections (STIs) other than HIV. WHO does not make any statements on minimum age, and PrEP can be used by adolescents, although additional support may be needed for adolescents to effectively use PrEP, and there is a minimum weight requirement for safety indicated on product labels.

This document focuses on long-acting injectable lenacapavir (hereafter referred to as “LEN”) as the newest PrEP method currently recommended by WHO and approved for use in [country].

As more PrEP methods become available, informed choice is an important factor to consider in client-provider interactions and decision-making, especially because clients who can choose a preferred product may be more likely to use it effectively.<sup>1</sup> Providing additional choices for PrEP and supporting clients to select their preferred methods offers the potential to increase uptake and effective use of PrEP. Beyond the prevention of HIV acquisition, PrEP also has additional user-identified benefits related to emotional, social, and physical well-being; these value-based preferences also inform method selection and can be incorporated in shared-decision counseling that centers a client’s desired experience while benefiting from PrEP. These guidelines include considerations for health care providers to support clients in making informed choices about their preferred PrEP methods. If possible, multiple PrEP products should be available to allow for informed choice.

Other PrEP products are being developed, tested, and reviewed. Guidance on additional approved PrEP products will be made available as appropriate. PrEP is complemented by other HIV prevention strategies, such as condom and condom-compatible lubricant use; post-exposure prophylaxis (PEP); harm reduction and treatment for injection drug use; effective antiretroviral treatment for partners living with HIV, as needed; and provider engagement with a client to understand what support or referrals might be valuable to support effective use can further reduce the likelihood of HIV acquisition.<sup>2,3</sup>

To prevent unwanted pregnancy *and* STIs other than HIV, it is important to use PrEP in combination with condoms and condom-compatible lubricants whenever possible. Effective contraception can prevent unintended pregnancy, but condoms are the only method that can prevent both pregnancy and most STIs with proper use.

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<sup>1</sup> McGuire C, Atieno MA, Hoke T, Jeckonia P, K’orimba K, Lorenzetti L, et al. PrEP method switching: Will it yield greater coverage of HIV protection? Applying lessons learned from family planning to guide future research in the context of PrEP choice. *Curr HIV/AIDS Rep*. 2024 July 24. Available [here](#).

<sup>2</sup> Injection drug use is mentioned in this guidance; however, first-line prevention strategies for people who inject drugs (PWID) are needle exchange and/or drug use harm reduction and treatment. Importantly, PWID may also have sexual exposures for which needle exchange and/or drug use harm reduction and treatment do not provide necessary prevention strategies.

<sup>3</sup> WHO. Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations [Internet]. Geneva: WHO; 2022 [cited 2022 Nov 15]. Available [here](#).

## Overview of LEN

Lenacapavir belongs to a class of ARVs called capsid inhibitors that reduce the ability of HIV virus to multiply by damaging the protein shell of the HIV cell during the viral life cycle. LEN delivers lenacapavir systemically, so the drug is absorbed throughout the body.

Lenacapavir is a first-in-class antiretroviral, with no other drugs commonly used for prevention or treatment. While some evidence suggests LEN use may lead to some antiretroviral resistance to capsid inhibitors, the high efficacy and rarity of breakthrough infections during clinical trials point to a low likelihood of antiretroviral resistance overall; available evidence suggests that capsid inhibitor regimens may still be effective even if resistance to lenacapavir develops.<sup>4</sup>

LEN is a long-acting injectable PrEP method. The dosing strategy for LEN involves a mandatory oral loading dose of two 300 mg tablets given on each of days 1 and 2, beginning on the day of the first injection (total oral loading dose of 1200 mg). The injectable component is delivered subcutaneously as two 1.5 mL injections (total injectable dose of 927 mg) on day 1. Possible injection sites include the abdomen or the thigh. A pair of follow-up injections are administered every 26 weeks if use continues.

Oral pills are not needed for follow-up injections, provided users return on time to follow-up appointments (26 weeks +/- two weeks after the previous injection). Individuals who return after 28 weeks and wish to continue LEN will need to receive the same loading dose with the oral tablets over two days.

Evidence from two randomized controlled trials shows LEN is highly effective at preventing sexual HIV acquisition and may be offered as an additional prevention choice as part of combination prevention approaches.<sup>5,6</sup> Neither trial explicitly included or reported data on people who inject drugs, though LEN is expected to be efficacious for parenteral exposure and research is now underway and expected to yield specific direct evidence. LEN showed no increase in adverse pregnancy or birth outcomes among reported pregnancies in the trial among cisgender women, and more data on pregnancy outcomes are anticipated. LEN may be suitable for clients seeking less frequent dosing or increased privacy around PrEP use, or for whom use of other PrEP options is difficult or not desired.

## Formulation of LEN

LEN consists of a mandatory oral loading dose at initiation of two 300mg tablets taken on day 1 with two injections of lenacapavir (1.5 mL each) at a dose of 927 mg, and two 300mg tablets provided to the client to be taken with them for use on day 2. On-time follow up dosing is two injections of lenacapavir (1.5 mL each) at a dose of 927 mg.

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## LEN Effectiveness

In clinical trials, LEN has been shown to be highly effective in cisgender adolescent girls and young women, cisgender, gay, bisexual and other men who have sex with men, and trans- and gender non-binary people at least 16 years of age. When used as directed, LEN greatly reduces HIV acquisition and is shown to be at least 96% effective. If a client is using LEN for HIV prevention, it is important they keep up with regular appointments for injections to make sure there is enough lenacapavir in their body to continue to prevent HIV. When a client misses a scheduled injection or discontinues LEN, concentrations of the medication in the body slowly decline. During this pharmacokinetic “tail,” LEN becomes gradually less preventative against HIV acquisition, and seroconversion may occur if the client continues to be exposed to HIV. For more information on the pharmacokinetic tail, refer to the [Stopping LEN](#) section.

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## Potential Side Effects of LEN

The most common side effects for LEN are nausea/diarrhea, headache, tiredness or injection site reactions (ISR). These side effects are usually mild. ISRs can include redness/bruising, pain, nodules, induration and swelling at the injection site. Mild or moderate ISRs, including the formation of nodules, are more common than other potential side effects, becoming less frequent and less severe over time as clients get used to the injection. Both indurations and nodules may resolve more slowly than other ISRs (several months to a year or more). Keloid formation has not been reported in study participants

For information on less common side effects, review the product label.

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- 4 Margot NA, Jogiraju V, Pennetzdorfer N, Naik V, VanderVeen LA, Ling J et al. Resistance analyses in heavily treatment-experienced people with HIV treated with the novel HIV capsid inhibitor lenacapavir after 2 years. *J Infect Dis.* 2025. doi: 10.1093/infdis/jiaf050
  - 5 Bekker LG, Das M, Abdool Karim Q, Ahmed K, Batting J, Brumskine W et al. Twice-yearly lenacapavir or Daily F/TAF for HIV prevention in cisgender women. *N Engl J Med.* 2024;391:1179-92. doi: 10.1056/NEJMoa2407001
  - 6 Kelley CF, Acevedo-Quinones M, Agwu AL, Avihingsanon A, Benson P, Blumenthal J et al. Twice-yearly lenacapavir for HIV prevention in men and gender-diverse persons. *N Engl J Med.* 2024. doi: 10.1056/NEJMoa2411858

# LEN and Other Drug Interactions

The use of LEN has not been associated with nephrotoxicity or hepatotoxicity. Thus, no liver or kidney function testing and monitoring are required during LEN initiation or follow-up. No dose adjustment is required in individuals with mild, moderate or severe renal impairment (creatinine clearance  $\geq$  15 mL/min). LEN has not been studied in individuals with end-stage renal disease; thus, it should be used with caution in these individuals.

After administration, LEN undergoes minimal metabolism. Drugs affecting LEN metabolism and preventing its use include moderate and strong inducers of drug metabolizing enzymes. At the same time, LEN is a moderate inhibitor of CYP3A4 and, therefore, affects drugs metabolized by CYP3A4, particularly those that have a narrow therapeutic range.<sup>7</sup> Upon discontinuation of LEN, residual concentrations of LEN may remain in the circulation for prolonged periods and could affect how other CYP3A4 substrates are metabolized, particularly those initiated within nine months after the last subcutaneous dose.

Table 1 summarizes interactions with selected key drugs and management strategies (if necessary). This information may be updated as experience in LEN implementation increases, and new data becomes available. Further interactions may be found online [here](#); the list of medicines here is not exhaustive and is subject to change.

## For consideration:

Dose adjustments may be included below based on national regulatory documents or include those listed by the US FDA, found [here](#).

**Table 1. Summary Of Drug-Drug Interactions with Lenacapavir**

Drug class	Interaction and management
<b>Antibiotics for treatment of tuberculosis</b> - Rifabutin - Rifampicin - Rifapentine	<b>Potential interaction, which requires dose adjustment</b>  Induction of CYP3A4 can substantially reduce LEN concentrations which may result in loss of its prevention efficacy.
<b>Anticonvulsants</b> - Carbamazepine - Phenobarbital - Phenytoin	<b>Potential interaction, which requires dose adjustment</b>  Induction of CYP3A4 can substantially reduce LEN concentrations, which may result in loss of its prevention efficacy.
<b>Illicit/recreational</b> - Ketamine	<b>Potential interaction, which may persist after discontinuation of lenacapavir</b>  Ketamine concentrations may increase due to inhibition of CYP3A4 by LEN and may increase side-effects associated with ketamine, such as respiratory depression and hallucinations.
<b>Erectile dysfunction</b> - Avanafil - Sildenafil - Tadalafil - Vardenafil	<b>Potential interaction, which may persist after discontinuation of lenacapavir</b>  Sildenafil, tadalafil and vardenafil concentrations may increase due to the inhibition of CYP3A4 by LEN.
<b>Gender-affirming hormones</b> - Estradiol - Conjugated estrogens - Ethinylestradiol - Medroxyprogesterone - Micronized progesterone - Testosterone	<b>No dose adjustment required</b>  LEN is a moderate inhibitor of CYP3A4 and could potentially increase exposure of the gender-affirming hormone, although to an extent that does not require dose adjustment.
<b>Hormonal contraceptives</b> - Ethinylestradiol - Etonogestrel - Levonorgestrel - Medroxyprogesterone - Norethisterone - Norgestrel	<b>No dose adjustment required.</b>  LEN is a moderate inhibitor of CYP3A4 and could potentially increase exposure of the contraceptive hormone, although to an extent that does not require dose adjustment.

<sup>7</sup> Gilead Sciences. Lenacapavir [package insert]. Foster City: Gilead; 2024 [cited 2025 July 1]. Available [here](#).



There are no known interactions between LEN and other recreational drugs or alcohol, but alcohol and drug use could affect the ability to attend necessary health appointments, potentially resulting in missed injections. If a client thinks that their use of alcohol or other substances is interfering or may interfere with effective use of LEN, the provider should engage the client to understand what support or referrals might be valuable to support effective use while also discussing additional prevention options, including other PrEP methods and the use of condoms and condom-compatible lubricant.

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## Contraindications for LEN Use

**LEN should not be provided to people with:**

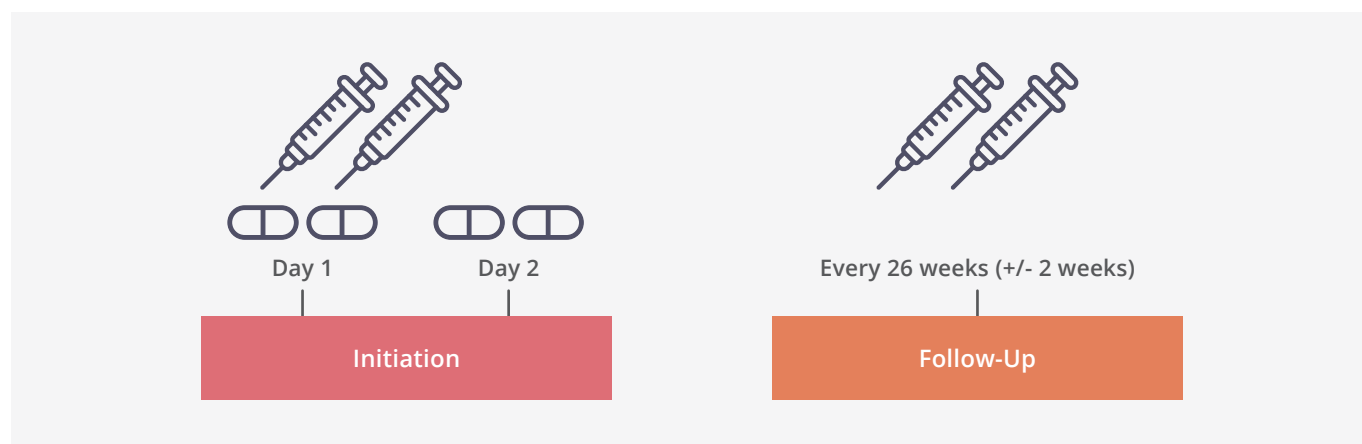
- An HIV-positive test result according to the national HIV testing algorithm
- Potential exposure to HIV in the past 72 hours (these clients should be offered PEP)
- Signs of acute HIV infection (AHI) [\[Box 1\]](#) AND potential exposure within the past 1 month
- Unwillingness or inability to commit to effectively using LEN

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## LEN Use

LEN is a PrEP method that requires both oral and injectable components at initiation (or reinitiation) followed solely by injections. LEN is a long-acting injectable PrEP method consisting of an oral loading dose taken over two consecutive days, with two tablets taken on day one with two initiation injections and two tablets provided to the client to be taken on day 2. It is a subcutaneous injection given at least 5cm from the navel on the abdomen, or on the thigh. The second injection should be given at least 10cm from the first injection site. After initiation, if an individual continues to use LEN for HIV prevention, LEN is administered every 26 weeks with two injections. The medication may stay in the body for at least 12 months after a client stops using LEN because of its long half-life, but at levels that may not prevent HIV.

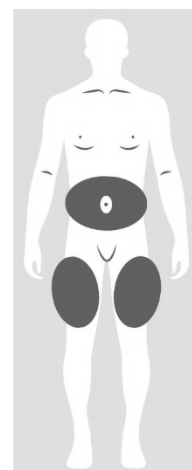
**Figure 1. LEN dosing schedule**



## Starting LEN

LEN can be given by providers in nationally approved health care cadres. The client should be provided with two LEN pills to take on the same day as the first two injections and provided with two tablets to take with them for use the following day. LEN is effective within a day of getting the first two injections and taking the first two pills.

LEN should be injected subcutaneously in either the abdominal or thigh area, at least 5 cm from the navel if in the abdomen and at least 10 cm from the first injection site (see image alongside). The provider should select the injection site in consultation with the client, prioritizing client preference with areas with enough skin and body fat to pinch to avoid injecting into the dermis. LEN preparation and injection steps are listed in Boxes 2 and 3. The provider can position the client on their back or in another position comfortable for the client. The two injection sites should be cleaned. It is best to inject the medication as soon as possible once the injection sites have been cleaned. After the injection, the provider can use dry gauze to apply gentle pressure to the puncture site and, if needed or requested by the client, apply an adhesive bandage.



### Box 1. Signs of AHI

- Fever
- Swollen lymph glands
- Skin rash
- Headache
- Sore throat
- Aches and pains
- Mouth sores

## Box 2. LEN Preparation

Steps for LEN preparation are as follows:

1. Prepare supplies needed for injection.
2. Inspect the vial to ensure yellow colored solution is free from particles and the expiry date has not passed.
3. Remove vial cap and wipe top of uncapped vial clean with alcohol wipe. Using the syringe with withdrawal needle, inject 1.5 ml of air into the vial before withdrawing all contents from the vial.
4. Exchange the withdrawal needle to the new injection needle prior to injection.
5. Push the syringe plunger to expel any air/air bubbles, leaving only 1.5 ml of solution in the syringe.

Repeat steps 1-5 for the second injection.

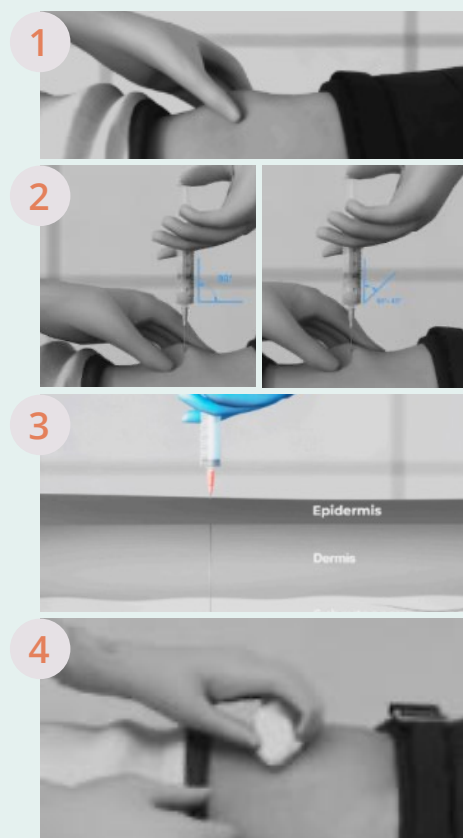


## Box 3. LEN Injection Technique

Steps for LEN Injection Technique

1. Gently pinch a broad portion of skin at the injection site, as pinching may give more subcutaneous tissue to target for the injection.
2. At the apex of pinched skin, insert the needle fully. It is preferable for the needle to be inserted perpendicular (at a 90° angle) to the skin, in clients with adequate subcutaneous tissue. For clients with minimal subcutaneous tissue, the needle may be inserted at an angle between 45°-90°. The needle should not be inserted at an angle less than 45°.
3. Slowly push the plunger to carefully perform the injection. Pause for several seconds after injecting. Remove the needle from the skin at the same angle it was inserted.
4. Apply dry gauze at the injection site and then replace it with a bandage.
5. Dispose of needle and syringe in sharps container.

Repeat steps 1-5 for the second injection.



## Stopping LEN

If a client decides to stop using LEN, they may stop receiving injections. The amount of lenacapavir in the blood remains at effective levels for at least six months after the final injections. After six months, the concentration of lenacapavir in the body falls below a preventative threshold.

The time starting six months after the last LEN injections when lenacapavir remains in the body but at levels that may not prevent HIV is known as the “tail period”. Data on HIV acquisition during the tail period is limited. For these reasons, quarterly follow-up visits, scheduled 9 and 12 months after the last LEN injection, are recommended for HIV retesting and reassessment of HIV prevention and other health needs.

As with all PrEP methods, if a client discontinues LEN, they should use another HIV prevention strategy, which may include using another PrEP method, during the tail period if exposure to HIV is possible, initiating the alternative strategy within 28 weeks of the last LEN injection.

## Missing a LEN injection

Adherence to the injection schedule is important to effective use of LEN. The window for follow-up injections is 26 +/- 2 weeks from the previous injections. A client who misses a scheduled visit should contact their health care provider immediately to get advice about how to continue using LEN or to talk about switching to a different HIV prevention strategy, which may include using another PrEP method.

**Suggested procedures for clients who miss a scheduled LEN injection are detailed as follows:**

Time since last injection	Recommended action for provider
≤ 28 weeks since last injection	Administer LEN injections as soon as possible and continue with follow-up injections every 26 weeks.
> 28 weeks since last injection	Consider the client as restarting LEN and assess the client for contraindications for LEN using the initiation procedure and, if contraindications are absent, restart the client on LEN by providing initiation injections and oral loading dose (two tablets for day 1 and two tablets provided to client to take on day 2), and scheduling follow-up injections 26 weeks later. Follow-up visits should be scheduled every 26 weeks thereafter.

## Restarting LEN

Clients who wish to restart LEN PrEP should contact their provider to discuss strategies for restarting LEN. If it has been more than 28 weeks since the last injections, clients will need to restart with the oral loading dose.

## Switching Between PrEP Methods and Simultaneous Use

Clients starting a particular PrEP product may decide later to switch to another option, for any number of reasons related to their preferences or product characteristics and it is important to maximize prevention effect where possible, even if it occasionally requires concurrent use of more than one PrEP method.

### Transitioning to LEN:

- **From oral PrEP:** Clients should continue using TDF-based oral PrEP throughout both days of LEN initiation.
- **From the dapivirine vaginal ring (DVR):** Clients should continue wearing DVR throughout both days of LEN initiation.
- **From CAB-LA:** If the last CAB-LA injection was CAB-LA Initiation injection one, clients should start LEN one month after that injection. If the last CAB-LA injection was initiation injection two or a follow-up CAB-LA injection, clients should start LEN two months after that injection.

### Transitioning from LEN:

- **To oral PrEP, the DVR, or CAB-LA:** Clients should insert the DVR, start CAB-LA or start TDF-based oral PrEP six months after the last LEN injection was administered, regardless of the type of LEN injection last administered.



# PREP INITIATION VISIT

Components of LEN PrEP initiation visits are like those for other PrEP methods. For most clients, PrEP can be initiated on the same day. However, in some scenarios, as outlined below, deferred PrEP initiation is recommended. Clients must meet criteria to begin PrEP use.

## They must be:

- HIV negative
- Not indicated for PEP
- Assessed for AHI
- Requesting PrEP or indicated for PrEP use
- Free from contraindications for use of their chosen PrEP method
- Willing and able to use PrEP as directed

## The four essential components of PrEP initiation visits are:

- 1) HIV testing and counseling,
- 2) Assessments,
- 3) PrEP counseling, and
- 4) PrEP prescription. For clients choosing LEN, there will be one initiation visit.

## COMPONENT 1: HIV Testing and Counseling

HIV testing and counseling should be conducted per national guidelines using rapid diagnostic tests. Same-day HIV testing is strongly suggested. If the test result is negative, a client can continue through the initiation visit and may be able to start PrEP. If their result is positive, the client must not be initiated on PrEP but should receive further testing per the national algorithm and, if the result is confirmed positive, the client should be immediately initiated on or referred for ART. If the test result is inconclusive, defer PrEP and follow the national algorithm/guidelines until a definitive HIV test result has been obtained. Further implementation research is needed to fully determine the role of HIV self-testing (HIVST) in delivering long-acting injectable PrEP such as LEN.

As part of HIV testing and counseling, clients should be counseled on combination HIV prevention and provided with condoms and condom-compatible lubricant.

### For consideration:

In some settings, it may be difficult to offer a client PrEP on the same day when they test negative for HIV. Some programs accept the results of tests conducted within the last three to seven days if a client has had no potential exposure to HIV since their test.



## COMPONENT 2: Assessments

The purposes of these assessments are to make sure a client:

- Is prescribed PEP, instead of PrEP, if they have had potential exposure to HIV within the last 72 hours;
- Has been assessed for AHI and if AHI possible, use of PrEP deferred pending re-testing;
- Is requesting PrEP/might benefit from PrEP; and
- Is free of contraindications for use of their chosen PrEP method. *Diagram 1* outlines the algorithm for ruling out HIV through HIV testing, and PEP and AHI assessment. Once HIV exposure or potential acquisition has been ruled out through these three steps, clinicians may assess for clinical contraindications to ensure the client is eligible for their chosen PrEP method.

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### Assess for PEP Indication

#### Clients exposed to HIV within the past 72 hours

If a client reports an exposure to HIV within the past 72 hours, screen for PEP indication instead of PrEP and provide PEP according to national guidelines. PEP should be offered as early as possible, ideally within 24 hours but not later than 72 hours after exposure.<sup>8</sup> Educate clients on the differences between PEP, PrEP, and ART and offer HIV exposure reduction counseling. After 28 days of PEP, a client may be transitioned from PEP to PrEP without a gap after receiving an HIV-negative test result and if they meet other criteria for PrEP use.

#### *Transitioning from PEP to PrEP*

Some people needing PEP will have repeated or ongoing potential exposures to HIV. Health care providers should discuss with people presenting for PEP whether they may benefit from and be interested in transitioning to PrEP after completing the PEP course in addition to exploring other HIV prevention strategies and products. In this way, PEP use can be an entry point to promote awareness, access, and use of HIV prevention strategies and products, including PrEP. Repeated PEP use can be an indication that a client may benefit from PrEP, though PrEP should not be restricted to only those clients with repeat PEP use.

Immediate transition to PrEP is preferable for individuals with ongoing potential exposures to HIV and the desire to take up PrEP. People who complete the 28-day PEP regimen and wish to use PrEP can start PrEP without a gap if they have a negative HIV test result on completion of PEP and do not have any contraindications to the chosen PrEP product.

PrEP may not be wanted or needed after every instance of PEP use. Some people at continuing likelihood of exposure may prefer not to take PrEP and may want to use other methods of HIV prevention, including PEP. Some exposures may be isolated events that do not require continuing prevention, such as a health care-associated exposure (for example, a needlestick injury) or some cases of sexual exposure, such as sexual assault.

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### Assess for Acute HIV Infection

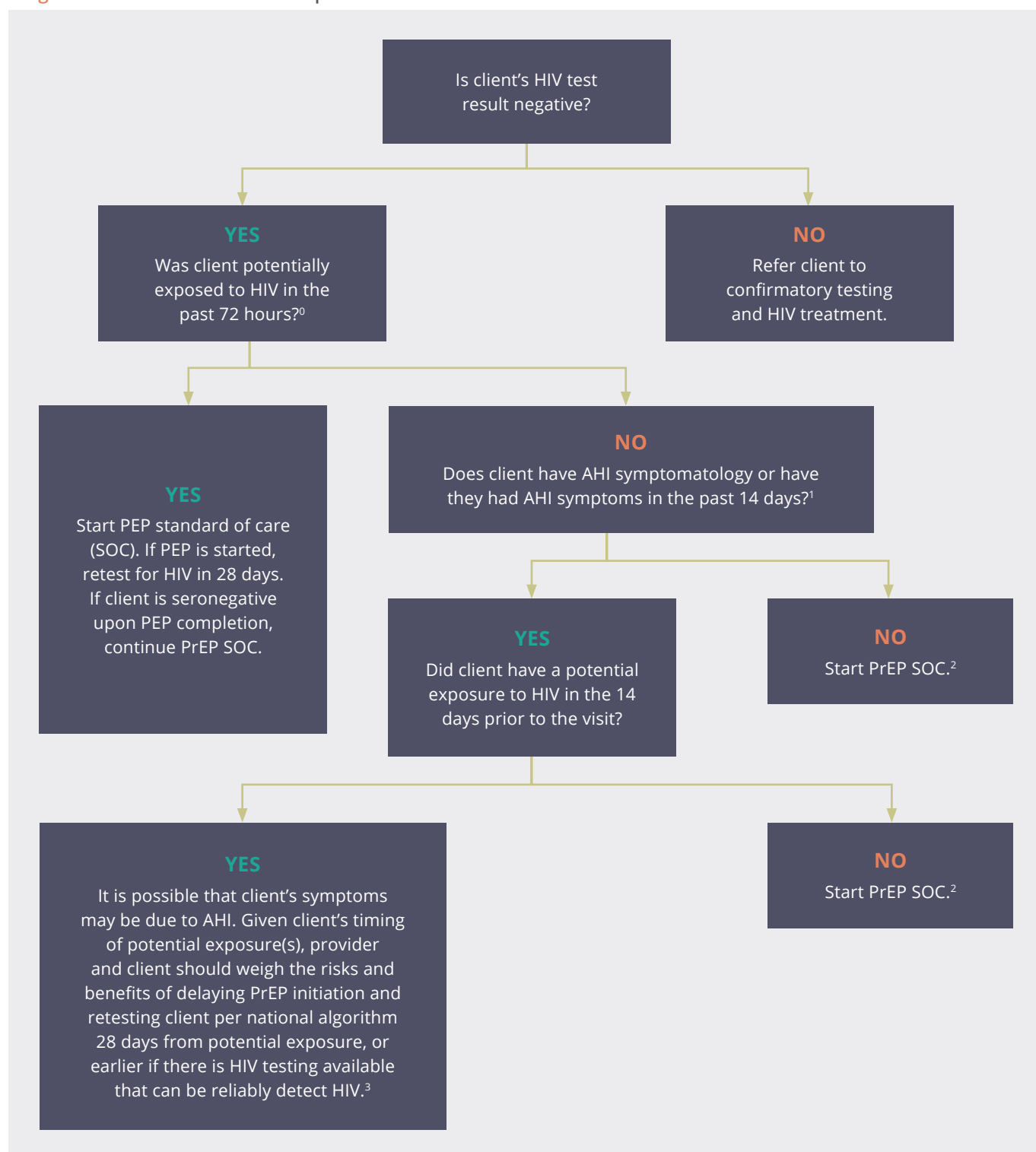
#### Clients suspected of having AHI

Two-thirds of people will have symptoms of AHI within two to four weeks of HIV acquisition.<sup>9</sup> If a client has or has had signs and symptoms of acute HIV infection (see *Box 1*) AND possible exposure to HIV in the 14 days prior to symptom onset, it is possible that the client's symptoms may be due to AHI, especially if a prevention method was not being used or not being used effectively. Given the client's timing of potential exposure(s), the provider and client should weigh the risks and benefits of delaying PrEP initiation and retesting the client in 28 days per the national algorithm, or earlier if HIV testing is available that can reliably detect HIV. Clients should be provided with HIV exposure reduction counseling, as well as sexually transmitted infection (STI) screening, diagnosis, and management, if available. If the client has an HIV-negative result after retesting and the client meets other criteria for PrEP use, the client can start PrEP.

<sup>8</sup> WHO. Guidelines for HIV post-exposure prophylaxis [Internet]. Geneva: WHO; 2024. Available [here](#).

<sup>9</sup> Letizia AG, Eller LA, Bryant C, Dawson P, Nitayaphan S, Kosgei J, et al. Clinical signs and symptoms associated with acute HIV infection from an intensely monitored cohort on 2 continents. *Medicine*. 2022;101(5):e28686.

**Diagram 1. PrEP initiation – HIV exposure and AHI assessment**



<sup>0</sup> An answer of "NO" to this question means no potential past exposure to HIV at all or potential HIV exposure that was 73+ hours ago.

<sup>1</sup> Two-thirds of people will have symptoms of AHI within two to four weeks of HIV acquisition. Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, and muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV or may be explained by an alternative cause.

<sup>2</sup> To make an informed choice prior to starting PrEP, the client should be aware that available HIV testing may not have been able to detect HIV if the client acquired HIV fewer than 28 days ago, and there is a possibility the HIV test may not have detected HIV if acquired beyond 28 days ago. The client should also be aware that although they do not have symptoms of AHI, they could be pre-symptomatic or be part of the one-third of individuals who do not develop symptoms of AHI within two to four weeks of acquiring HIV.



## Assess Client's Request for PrEP or if Client May Benefit from PrEP

### Client Request

Clients who request PrEP should be counseled on and offered PrEP if HIV has been ruled out to the extent possible by HIV testing and assessments for PEP and AHI, and they are free from contraindications for the use of their chosen PrEP method. Clients should not have to qualify or explain their request in detail. *Requesting PrEP has been shown to be an indicator of client need for PrEP.*

### Clients Who May Benefit from PrEP

When a client is not asking for PrEP, the provider may need to initiate a conversation about what behaviors may indicate that a client may benefit from PrEP. Any tool used in PrEP initiation and continuation counseling should support clients to understand their likelihood of exposure to HIV; prompt discussion of available PrEP methods or other HIV prevention strategies; and support decision-making. These tools should not be used to ration PrEP or to determine a client's eligibility and they are not required. Epidemiological measures such as population-level HIV incidence may guide programmatic targeting but should not be used as criteria for PrEP access.

### Clients who report any of the following may benefit from using PrEP:

- Vaginal or anal sex without condoms with:
  - More than one partner
  - A partner with potential HIV exposures
    - Some clients' potential exposures to HIV include being exposed through a partner who may have exposures to HIV through sexual or injection practices. Exploring the potential HIV exposures of a client's sexual partners with the client may be particularly important for adolescent girls and young women, people who have sexual partners who are members of key populations, and pregnant and breastfeeding people.
    - A partner living with HIV who has not been on effective HIV treatment (on ART for less than six months or has inconsistent or unknown adherence)
- Recent or current STI diagnosis (based on lab test, syndromic STI treatment, or self-report)
- Recent or current PEP use
- Sharing of injection material and/or equipment

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## Assess for Contraindications for Use of Client's Chosen PrEP Method

Clients must be assessed for contraindications for the use of their chosen PrEP method. Since some clients will decide on a method during PrEP counseling, this portion of the assessment may occur before, during, or after counseling takes place. Contraindications for LEN PrEP are found in [Contraindications for LEN Use](#) above

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## COMPONENT 3: PrEP Counseling

Education and counseling for clients considering PrEP, or clients already on PrEP, are important to ensure clients can make informed choices and effectively use PrEP.

**PrEP counseling should be based on the following right to health-based principles:**

- Be client-driven and person-centered, based on their needs, resources, and preferences
- Be based on a foundation of respect and include an open, honest relationship between provider and client
- Recognize that behavior change can take time
- Validate and normalize client concerns, seek to affirm and encourage client efforts, and not be prescriptive or judgmental
- Focus on identifying small wins and achievable next steps in reducing potential exposures and/or making effective use easier
- Include contingency planning when common barriers are encountered
- Promote choice among available options based on client preferences and acceptability

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### Topics for Initial PrEP Counseling

- Sexual behaviors
- Alcohol and drug use
- Plan for preventing HIV and other STIs
- Mental health
- Prevention needs and interest in and willingness to take PrEP
- Experience of gender-based violence (GBV), including intimate partner violence (IPV)
  - Provide appropriate GBV and IPV response, including first-line support and referral where necessary, and support clients to identify ways to effectively use and continue PrEP for as long as the client wishes to use it as part of their HIV prevention strategy. *(Clients experiencing GBV, including IPV, should not be prohibited from receiving PrEP if they can effectively use it.)*
- Contraceptive needs
- Key messages for counseling PrEP (for specific messaging on LEN see [Table 3](#) in [Annex](#))

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## COMPONENT 4: PrEP Prescription

Clients who choose LEN will receive the two initiation injections and take two tablets at the first visit and be provided with two oral pills to take the next day. Their first follow-up visit should be scheduled for 26 weeks later. If needed, a client's follow-up visit can be as early as 24 weeks and as late as 28 weeks after LEN initiation.

When possible, follow-up visits should be coordinated with visits for other services to reduce the number of times a client must return to receive services.

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### Additional Components of PrEP Initiation Visit

Table 2 summarizes the components that could be offered alongside PrEP services as part of comprehensive, person-centered care, depending on a client's needs and preferences. This list is not exhaustive, and services needed will vary by individual and population. PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services.

**Table 2. Additional Components of PrEP Initiation Visit**

Component	Action
<b>Screening, testing, and treatment of other STIs</b>	<p>PrEP can be used if the client has STIs other than HIV and during treatment of STIs other than HIV. Manage STIs per STI standard treatment guidelines. If testing is not possible, symptomatically manage STIs per STI standard treatment guidelines.</p> <p>PrEP should still be provided even if these services are not available, are delayed or if the client is unable to or does not wish to access these services.</p>
<b>Screening, testing, and treatment of hepatitis B</b>	<p>Testing clients using PrEP for hepatitis B at or within three months of PrEP initiation is strongly suggested where feasible.</p> <p><b>LEN</b> is not contraindicated for people with hepatitis B, but it has not been extensively studied in people with active hepatitis B so close monitoring is recommended.</p> <p>Availability of or access to hepatitis B testing should not be a barrier to PrEP initiation or use. If hepatitis B testing is conducted, PrEP can be initiated before the results are available.</p>
<b>Screening, testing, and treatment of hepatitis C</b>	<p>Testing for hepatitis C is strongly encouraged at or within the first three months of PrEP initiation and every 12 months thereafter where PrEP services are provided to populations with increased likelihood of hepatitis C acquisition.</p> <p><b>LEN</b> is not contraindicated for people with hepatitis C, but it has not been extensively studied in people with untreated hepatitis C so close monitoring is recommended.</p>
<b>Kidney function assessment</b>	Kidney function measurement is not suggested for use of the <b>LEN</b> .
<b>Liver function testing</b>	Liver function testing is not suggested for use of <b>LEN</b> .
<b>Pregnancy testing and provision of contraceptives</b>	<p>Assess fertility intentions and offer pregnancy testing and contraception or safer conception counseling. Regular pregnancy testing is recommended for clients who are using PrEP and have the potential to become pregnant.</p> <p>If a client is pregnant, link them to antenatal care and pregnancy options counseling (see <a href="#">Management of Clients in Specific Situations</a> below).</p> <p>PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services. These services should not be barriers to accessing PrEP.</p>
<b>Provision of GBV services, including IPV services</b>	<p>Clients who are experiencing GBV, including IPV, should be provided appropriate services as needed and available.</p> <p>PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services.</p>
<b>Assessment for mental health and substance abuse disorders and provision of supportive services or referrals as needed</b>	<p>Screen for mental health concerns, including depression and substance abuse disorders, which might increase potential HIV exposure or affect effective use of PrEP, and provide or link clients to follow-up services as needed. Clients with mental health or substance use concerns should not be prohibited from receiving PrEP if they can effectively use PrEP.</p> <p>PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services.</p>
<b>Provision of or referral to voluntary medical male circumcision (VMMC) services</b>	<p>Clients who may benefit from VMMC can be provided with or referred to VMMC services in alignment with national guidelines.</p> <p>PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services.</p>
<b>Screening for and treatment of noncommunicable diseases</b>	<p>Clients may have additional health needs that may come up during a visit with a health care provider or may be discovered through further assessment. Provide clients with relevant health care services or refer them to appropriate services as needed and available.</p> <p>PrEP should still be provided even if these services are not available or if the client is unable to or does not wish to access these services.</p>



# PREP FOLLOW-UP VISITS

Components of LEN PrEP follow-up visits are like those for other PrEP methods. For clients using LEN, follow-up visits will be every 26 weeks and should be scheduled during the initiation visit. Follow-up reminders should be sent **[insert timeframe]** in advance. Clients who miss their appointments should be followed up with within **[insert timeframe]** of a missed appointment.

Younger clients using PrEP and clients with other health, mental, emotional, and social needs may benefit from more frequent contact with PrEP providers.

**PrEP follow-up visits have four essential components:**

- 1) HIV testing and counseling,
- 2) Assessments,
- 3) PrEP counseling, and
- 4) PrEP prescription refills, as described below.

## COMPONENT 1: HIV Testing and Counseling

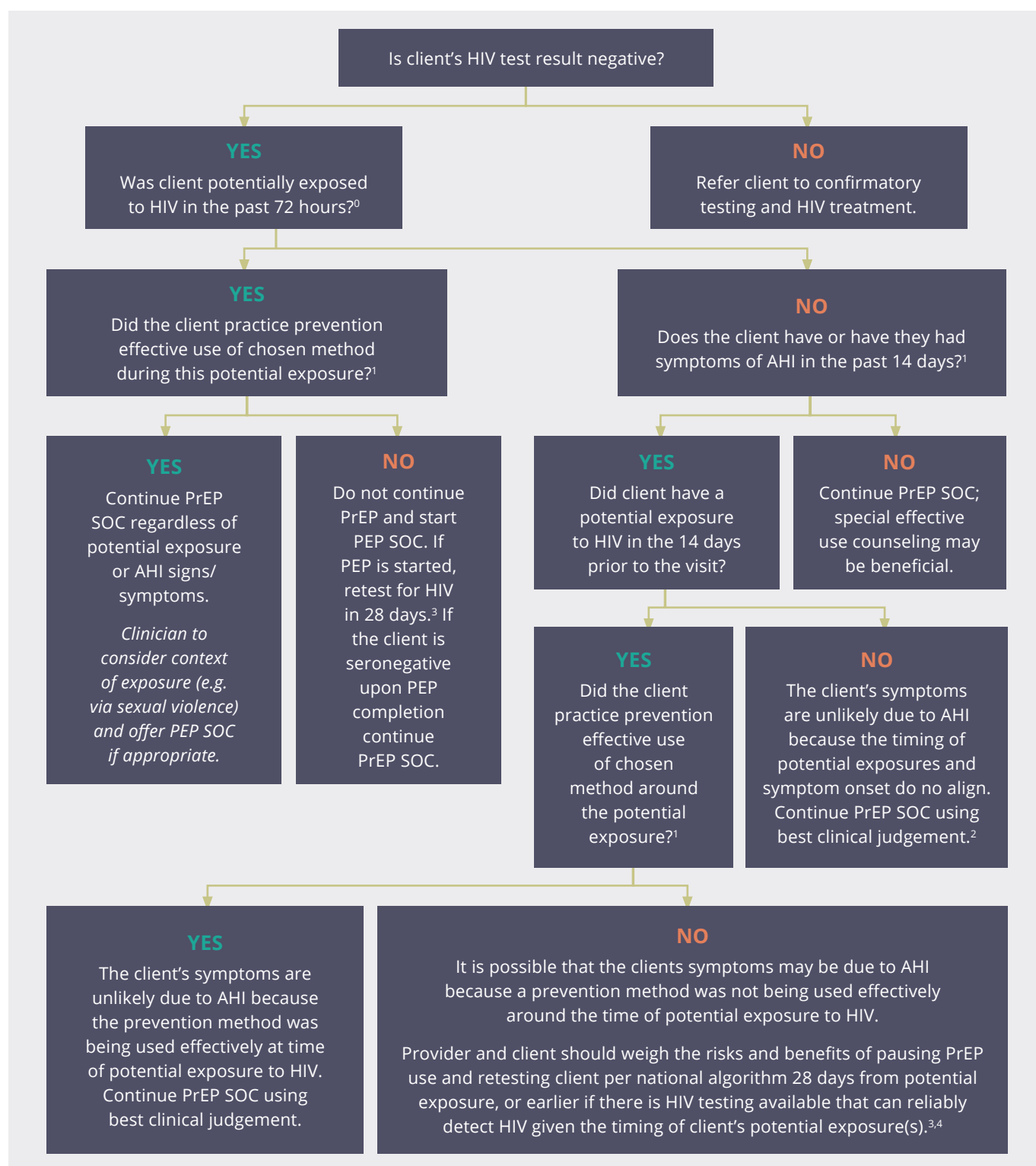
HIV testing and counseling should be conducted per national guidelines using rapid diagnostic tests. Further implementation research is needed to fully determine the role of HIVST in delivering long-acting injectable PrEP such as LEN.

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## COMPONENT 2: Assessments

At each follow-up visit, clients should be assessed for effective PrEP use and provided with support to identify and address challenges with effective PrEP use. It is essential that this be done in an open-ended, nonjudgmental manner. A neutral assessment of PrEP use allows for a constructive discussion that can support the client in finding solutions to effective use challenges. If the client has not used the PrEP method effectively or consistently enough to achieve prevention, the client should be assessed for PEP indication and symptoms of AHI. *Diagram 2* outlines the algorithm for these assessments.

**Diagram 2. PrEP Follow-Up – HIV Exposure, AHI, and Prevention Effective Use Assessment**



<sup>0</sup> An answer of “NO” to the question “Potentially exposed to HIV in past 72 hours?” means no potential past exposure to HIV at all or potential HIV exposure that was 73+ hours ago.

<sup>1</sup> Prevention effective use for LEN: Last injection was ≤ 28 weeks ago.

<sup>2</sup> Two-thirds of people will have symptoms of AHI within 2–4 weeks of HIV acquisition. Signs/symptoms mimicking acute HIV infection (sore throat, fever, sweats, swollen glands, mouth ulcers, headache, rash, and muscle aches) are commonly due to illnesses other than HIV; providers need to use discretion in determining whether the symptomatology is consistent with HIV or may be explained by an alternative cause.

<sup>3</sup> If HIV testing that can reliably detect HIV given these clients’ potential exposures and time frames is available, PrEP may be started earlier than 28 days if results are nonreactive.

## COMPONENT 3: PrEP Counseling

In addition to re-enforcing any of the key messages and counseling topics discussed at initiation, as needed, (for specific messaging on LEN see [Table 3 in Annex](#)), providers should discuss:

- Any side effects or adverse drug reactions the client has experienced (and manage them as needed — see [Management of Side Effects and Adverse Drug Reactions](#) below)
- If there is ongoing exposure to HIV and whether the client feels continued PrEP use is necessary
- Additional complementary sexual and reproductive health counseling, including counseling on STI prevention, contraception, and GBV

## COMPONENT 4: PrEP Prescription Refill

For clients using LEN, schedule the next follow-up visit 26 weeks later. If needed, a client's follow-up visit can be as early as 24 weeks and as late as 28 weeks after the previous injection. When possible, follow-up visits should be coordinated with visits for other services to reduce the number of times a client must return to receive services.

### Potential Components of PrEP Follow-Up Visits

Potential components of PrEP follow-up visits are the same as the potential components for initiation visits.

#### *Unscheduled PrEP Visits*

**For consideration:** Procedures for unscheduled visits might include:

- Determining whether the reason for the visit is PrEP-related or not, e.g., adverse drug reactions
- Assessing and managing the reason for the unscheduled visit according to national guidelines, e.g., acute or chronic illness, exposure to HIV while not using PrEP effectively, worsening existing condition(s)
- Providing HIV exposure reduction and PrEP effective use counseling
- Agreeing on a follow-up schedule

#### *Discontinuing PrEP Use*

The duration of PrEP use may vary, and individuals are likely to start and stop PrEP depending on their individual needs and assessment of potential HIV exposures at different periods in their lives, as well as changes in relationships and behaviors. Ideally, a client will inform their service provider when they want to discontinue PrEP. Often, however, clients may not return to their provider or the provider is informed after a client has already discontinued PrEP. It is therefore important that clients are informed during initiation and continuation visits about stopping PrEP safely (or stopping and restarting as appropriate).

**During counseling, providers should discuss with clients when it may be appropriate to discontinue PrEP. PrEP use may be discontinued for any of the following reasons:**

- Client request
- Positive HIV test (clients who seroconvert while on PrEP should be linked to care and initiated on ART in line with national guidelines)
- No longer likely to be exposed to HIV
- Persistent side effects that are not manageable
- Decision to switch to another HIV prevention strategy
- Starting use of contraindicated medications

Instructions on how to discontinue PrEP are included in information about each method's use above and in the counseling messages.

#### *Restarting PrEP Use*

Individuals restarting PrEP will need to be tested again for HIV and free of any contraindications for their chosen PrEP method. Clients restarting LEN will need to start again with the oral loading dose and injections as if starting for the first time.



# MANAGEMENT OF CLIENTS IN SPECIFIC SITUATIONS

This section outlines the management of clients in specific situations.

## Management of HIV Seroconversion

If a client seroconverts while on PrEP or after starting PrEP (even if not taking PrEP or not taking PrEP consistently):

- Discontinue PrEP use immediately.
- Confirm using national testing algorithm.
- Immediately link to care and initiate on ART (per national ART guidelines).
- Document seroconversion and possible reason for seroconversion (non-effective use, stopped taking PrEP, or PrEP failure, i.e., breakthrough HIV while adherent to PrEP) and, if available and indicated, link to HIV drug resistance testing.

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## Management of Side Effects and Adverse Drug Reactions

Side effects should be managed symptomatically. Counseling to support management of side effects should be provided. Any side effects should be recorded in client records and **[relevant forms]** regardless of severity. Severe adverse reactions, both injection site and non-injection site related, are rare in LEN exposure to date. Consult **[clinical staff cadre]** if these occur. Complete the national **[adverse drug reaction form]** and report per standard operating procedures.

In some cases, side effects may cause a client to discontinue PrEP use. If PrEP is discontinued, record the outcome in the PrEP register. Side effects and potential adverse drug reactions for each method are found in the overviews of each method above.

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## Pregnancy and Breastfeeding

Given the increased likelihood of HIV acquisition during pregnancy and the postnatal period, as well as reassuring safety data, PrEP use is a reasonable option for people who are pregnant, breastfeeding, or conceive while taking PrEP.

LEN is likely safe to continue during pregnancy or breastfeeding though research is ongoing. The decision to start, continue or discontinue PrEP when someone becomes pregnant is a choice made by the individual after a discussion on risks and benefits with a provider.

Data are emerging on use of LEN during pregnancy and breastfeeding, though available evidence shows LEN likely has little to no effect in terms of adverse pregnancy or birth outcomes when compared to oral PrEP. In one randomized controlled trial, participants who became pregnant could continue the study drug upon receipt of counseling and informed consent – available data from 184 pregnancies reported among participants using LEN have shown no increase in adverse pregnancy or birth outcomes.<sup>10,11,12</sup> Further, no dose adjustment is likely to be required during pregnancy. Additional pharmacokinetic studies on LEN during pregnancy and breastfeeding will be available soon.

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<sup>10</sup> Bekker LG, Das M, Abdool Karim Q, Ahmed K, Batting J, Brumskine W et al. Twice-yearly lenacapavir or Daily F/TAF for HIV prevention in cisgender women. N Engl J Med. 2024;391:1179-92. doi: 10.1056/NEJMoa2407001

<sup>11</sup> Kelley CF, Acevedo-Quinones M, Agwu AL, Avihingsanon A, Benson P, Blumenthal J et al. Twice-yearly lenacapavir for HIV prevention in men and gender-diverse persons. N Engl J Med. 2024. doi: 10.1056/NEJMoa2411858

<sup>12</sup> Bekker L-G, Moodley D, Harkoo I, Kigozi G, Louw CE, Malahleha M et al. Inclusion of pregnant and lactating people in the PURPOSE 1 study: efficacy, safety, and pharmacokinetics. 13<sup>th</sup> International AIDS Society Conference on HIV Science; 12-17 July; Kigali, Rwanda, 2025





# WHO CAN DELIVER PREP AND WHERE?

PrEP implementation can be integrated in any setting with appropriately trained individuals who have been authorized to provide components of PrEP initiation and/or follow-up visits according to national guidelines. It is important that places where PrEP is provided also have systems and tools in place for completing all the necessary steps of PrEP initiation and follow-up and the monitoring, documentation, and reporting of PrEP use.

**For consideration:** Because the roles and responsibilities of different cadres of health care providers can change over time, it may be beneficial to not specify which cadres are involved in specific aspects of PrEP service delivery. This allows for task-sharing among nonclinical (or less specialized) cadres to occur and supports further movement of PrEP from health facilities into the community. Alternatively, in some cases it could be useful to specify certain providing groups, such as peer providers, where the type of provider is critical to client acceptability of PrEP. Likewise, it may be beneficial not to include an exhaustive list of possible PrEP service delivery locations in guidelines to avoid limiting programmatic expansion and differentiated service delivery. Some service delivery locations may include: one-stop shops; drop-in centers (including in community and facility settings); HIV clinics (for people without HIV who have a partner or partners who do not have suppressed viral load or when viral suppression is unknown); antenatal care and maternal, newborn, and child health clinics; family planning, reproductive health, and STI clinics; mobile health clinics; community settings meeting the criteria for initial client assessment and evaluation (e.g., integrated prevention centers and youth-friendly outlets); and primary care settings, as well as virtual or blended in-person and virtual models.

**Table 3. Key Messages for Counseling on LEN PrEP**

Topic	Key messages
<b>Effectiveness of LEN</b>	<p><b>LEN</b> is highly effective at preventing HIV through sexual exposure in cisgender adolescent girls and young women, cisgender, gay, bisexual and other men who have sex with men, and trans- and gender non-binary people at least 16 years of age. When used as directed, LEN greatly reduces HIV acquisition and is shown to be at least 96% effective.</p> <p>When choosing a PrEP method, it is important to consider which method(s) will work best for you to prevent HIV during the types of exposures you anticipate, among other factors.</p> <p><b>LEN</b> is effective for sexual exposures and, as systemic products, may also cover parenteral exposures.</p>
<b>Starting LEN</b>	<p>If you choose to start PrEP, it is particularly important to try to avoid potential exposure to HIV until adequate drug levels are achieved by using condoms with condom-compatible lubricant and using sterile and non-shared injection-related materials.</p> <p><b>LEN</b> is injected into the abdomen or thigh. The first two injections occur at your initiation visit, and you will also be given an oral loading dose to take over two days. The oral loading dose consists of two tablets for day 1, that you will take when you receive your initiation injections, and two tablets provided to you to take the next day, on day 2. LEN is effective within a day of getting the first two injections and taking the first two pills. The medication will stay in the body for at least 26 weeks after each pair of injections, but then levels decline and may not prevent HIV acquisition.</p>
<b>Stopping LEN</b>	<p>When you stop getting LEN injections every six months, the drug lenacapavir can remain in your body for about a year, but after six months it will not be at high enough levels to prevent HIV. During this time, if you acquire HIV you may be at risk of negative clinical outcomes, including HIV drug resistance, meaning some medicines used to treat HIV may be less effective or not work at all. If you decide to stop your LEN injections, we should talk about transitioning you to another PrEP method or another HIV prevention strategy for as long as exposure to HIV is possible. For these reasons, quarterly follow-up visits, scheduled 9 and 12 months after the last LEN injection, are recommended for HIV retesting and reassessment of HIV prevention and other health needs.</p> <p>We do not yet have enough information about pregnancy and breastfeeding during the tail period; therefore, if you are thinking of becoming pregnant or don't want to use contraception during the tail period, we should discuss what options will be best for you.</p>
<b>Missed LEN injection visit</b>	<p><b>LEN</b> follow-up visits are every 26 weeks with two weeks on either side to adjust to your needs. If you miss a scheduled visit, it is important to contact your health care provider immediately and schedule an appointment for the missed visit as soon as possible. If keeping to the LEN dosing schedule is not working for you, we can discuss changing to a different PrEP method or HIV prevention strategy.</p>
<b>LEN and alcohol or other recreational drugs</b>	<p>Taking LEN while you are using alcohol or most recreational drugs will not harm you, though there are potential interactions between LEN and ketamine which may continue after you stop taking LEN. These interactions can lead to increased side effects associated with ketamine.</p> <p>Alcohol or other recreational drugs may make it challenging to use PrEP correctly, such as by causing you to miss an appointment, so make a plan to continue using PrEP effectively if you use alcohol or other substances. We can talk about planning together if that would be helpful.</p>
<b>LEN and other medications</b>	<p>The drugs in some LEN may interact with other medications you may take. Are you taking any medications?</p>

**LEN, pregnancy, and breastfeeding**

**LEN** does not prevent pregnancy. To avoid unintended pregnancy, use a contraceptive method.

The likelihood of acquiring HIV is higher during pregnancy and the postnatal period. Taking any of the available PrEP methods while you are pregnant or breastfeeding will not hurt you or your baby. Available data suggests that LEN is likely safe during pregnancy and breastfeeding, but research is ongoing. Because HIV can be transmitted during pregnancy and breastfeeding, taking PrEP during this time prevents both you and your baby from acquiring HIV. It is your choice to start, continue, or stop PrEP when you become pregnant, and we can discuss the risks and benefits as you make the best decision for you and your baby.

**PROVIDER NOTE:** If a client is pregnant, link them to antenatal care or pregnancy options counseling (see *Management of Clients in Specific Situations* above for more information on PrEP for clients who are pregnant or breastfeeding and refer to national guidance).

**No STI prevention other than HIV**

**LEN** reduces the likelihood of HIV acquisition but does not prevent any other sexually transmitted infections (STIs). To prevent other STIs, use a condom and if needed, condom-compatible lubricant, correctly whenever you have sex, or as often as possible. It is important to regularly test for STIs, especially if you are not able to use condoms consistently.<sup>13</sup> If you experience discharge from the penis or the vagina that has a bad odor, causes irritation, or is a different color/amount than usual; bleeding that is not your period; or bumps, warts, swelling, redness, rash, or severe itching on or near your genitals, mouth, or anus, these could be signs that you may have an STI and should see a health care provider as soon as possible and abstain from sexual contact if you can.

**Side effects**

Some people who use LEN may experience side effects. The most common side effects for LEN are nausea/diarrhea, headache, tiredness or injection site reactions (ISR). These side effects are usually mild. ISRs can include redness/bruising, pain, nodules, induration and swelling at the injection site. Mild or moderate ISRs, including the formation of nodules, are more common than other potential side effects, becoming less frequent and less severe over time as clients get used to the injection. Both indurations and nodules may resolve more slowly than other ISRs (several months to a year or more). Keloid formation has not been reported in study participants

If having a visible injection site reaction or one that can be felt is of concern to you, please let me know and we can discuss ways to approach this for you.

Some people taking PrEP report positive effects on physical, emotional, or mental wellbeing. These include increased feeling of control over one's health and community belonging, and reduced anxiety as fear of HIV acquisition has decreased with PrEP use.

**Switching from LEN to other HIV prevention strategies, including other PrEP methods**

It is okay to stop LEN and switch to another HIV prevention strategy, including another PrEP method. Depending on the strategy you would like to switch to, we can discuss the best way to switch safely and effectively.

**Beyond PrEP, some other strategies that can reduce your likelihood of acquiring HIV include:**

- Using condoms and condom-compatible lubricant consistently
- Accessing PEP as early as possible, ideally within 24 hours but not later than 72 hours of potential exposure to HIV
- Having other types of sex that come with no or nearly no likelihood of HIV acquisition (such as mutual masturbation or oral sex)
- Receiving screening, diagnosis, and treatment for other STIs (left untreated, other STIs can increase the likelihood of HIV acquisition when exposed to HIV)
- Receiving voluntary medical male circumcision
- Accessing drug harm reduction and treatment services
- Ensuring that a partner living with HIV has been on effective ART for at least six months, has an undetectable viral load, and remains adherent to ART

<sup>13</sup> WHO. Implementation tool for pre-exposure prophylaxis of HIV infection – Integrating STI services. [Internet]. Geneva: WHO; 2022 [cited 2022 November 15]. Available [here](#).

**LEN follow-up visits** With LEN, you will have follow-up visits every 26 weeks if you continue to use it. It is important that you attend follow-up visits for the following reasons:

- To get support on effective use and managing side effects and to address other concerns you may have
- To verify your HIV status and, if positive, be referred for effective treatment and reduce the likelihood of drug resistance. Between now and your next visit, if you experience sore throat, fever, sweats, swollen glands, mouth ulcers, rash, or muscle aches, please contact me or come back here for a follow-up visit.

Do you have any upcoming travel, or do you anticipate any other challenges with returning for regular visits that we can discuss and maybe help you plan for?

**For consideration:** Many settings are implementing strategies to reduce the number of times clients using PrEP need to return for follow-up visits while ensuring they have access to ongoing care, including HIV testing. These strategies may include the deployment of community health workers, mobile clinics, pharmacy models, the use of HIV self-testing, and many others. This section may need to be modified based on how differentiated service delivery for clients using PrEP is structured in your country.

**Partner disclosure** People have different reasons for sharing or not sharing their PrEP use with their partner(s). Generally, individuals who can disclose their PrEP use with their partners can use it more effectively. If you would like, we can discuss your thoughts on sharing or not sharing your PrEP use together. If you choose not to tell your partner, we can also discuss your plan if your partner happens to learn about your PrEP use.

**PROVIDER NOTE:** Assess client's experience of gender-based violence (GBV), including intimate partner violence (IPV). If the client discloses that they have experienced or are at risk of GBV, including IPV, provide first-line support and make referrals as appropriate. Discuss how violence and fear of violence affects their potential HIV exposures and prevention behaviors and discuss ways they can stay safe and protect themselves in the context of their relationship(s). Although LEN may be an option for clients concerned about IPV due to their discreet natures, clients who wish to keep LEN use private should be counseled on the possibility of visible injection site reactions and be assisted with a plan to implement should this occur.

Supportive LIVES (Listen, Inquire, Validate, Enhance safety, and Support) tools for routine enquiry can be found [here](#). While the job aid specifies oral PrEP, it is applicable for clients using any PrEP method.





# **SOUTH *TO SOUTH* LEARNING NETWORK**

*Reimagining HIV Prevention*

