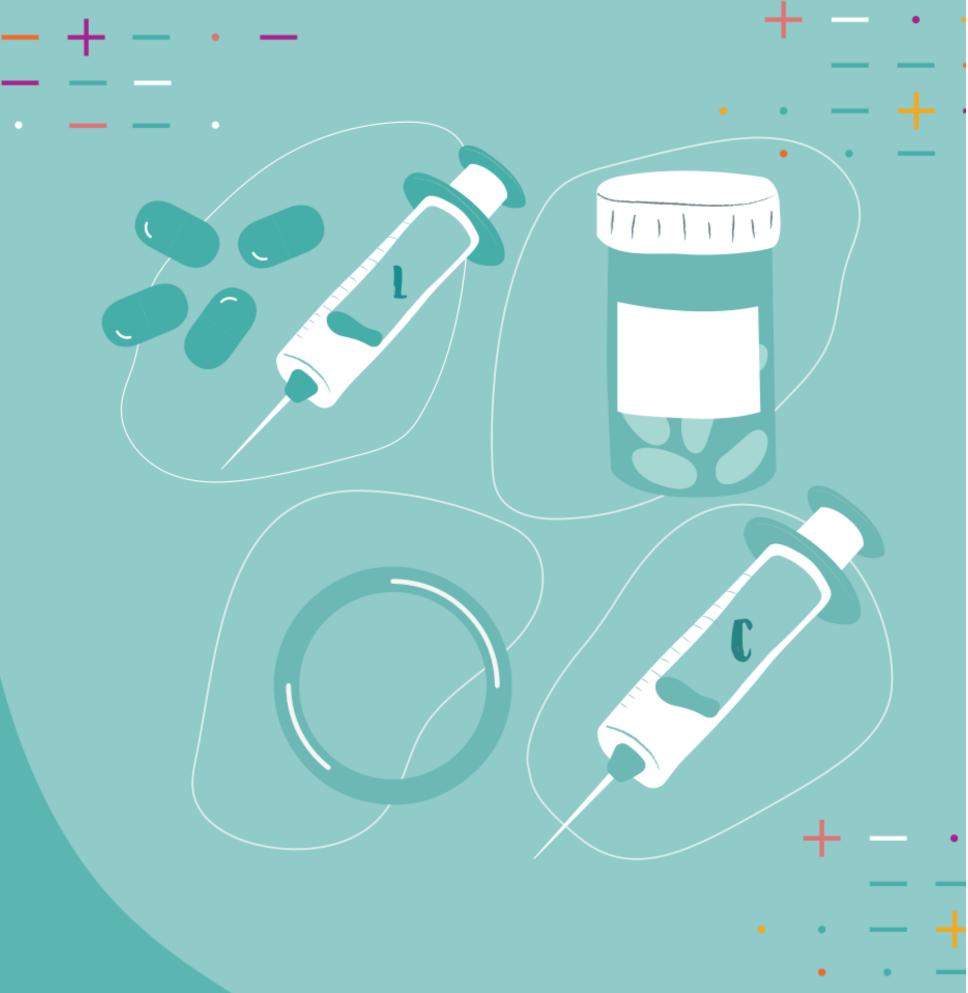
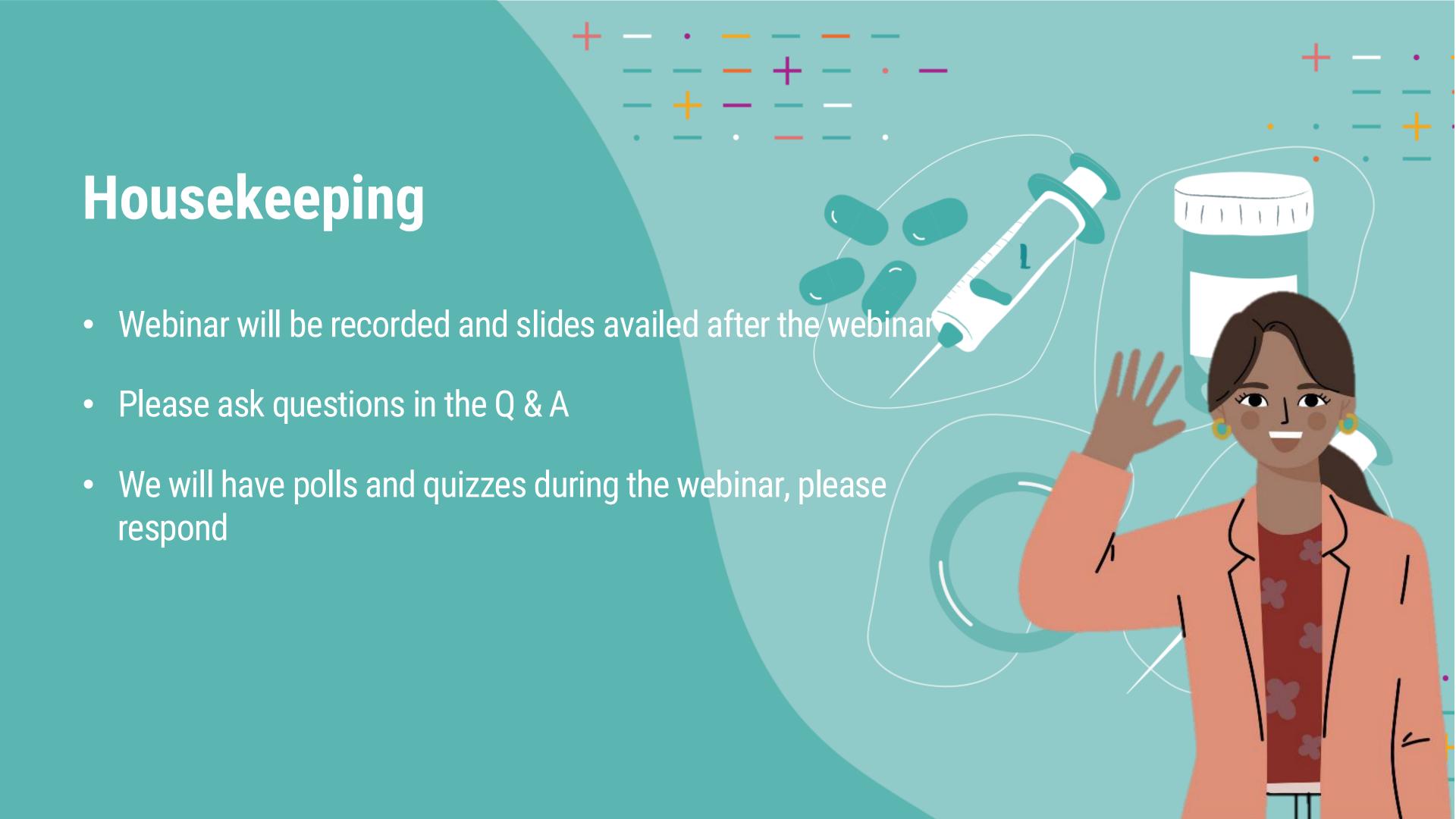


PROVIDER TRAINING TOOLKIT ON USE OF ORAL AND LONG-ACTING HIV PREP

Applying the PrEP Provider Training Toolkit to Support Clinical Decision-Making



OCTOBER 8, 2025



Agenda

• Overview of Training Toolkit:

Tigistu Adamu Ashengo, Jhpiego

- Principles of PrEP Delivery: Michelle Rodolph
- Case Study: "Amina's Journey":

Elizabeth Irungu, Jhpiegio & Heather-Marie Schmidt, WHO

- Adaptations for local LEN rollout: Elizabeth Irungu, Jhpiego
- Q+A



Overview of the Training Toolkit

Tigistu Ashengo, Jhpiego

special thanks to Jason Reed

PROVIDER TRAINING TOOLKIT ON USE OF ORAL AND LONG-ACTING HIV PRE-EXPOSURE PROPHYLAXIS (PREP)

This training toolkit is designed to help clinicians gain the knowledge and skills to provide multiple HIV PrEP methods, including:

- Oral PrEP
- Long-acting Cabotegravir (CAB-LA)
- Dapivirine Vaginal Ring (DVR)
- Lenacapavir (LEN)



The training toolkit covers key clinical topics in 4 modules:

Lesson 1:

PrEP Product Formulations and Evidence for Protection Against HIV

Lesson 2:

Determining Clinical Eligibility/ Assessing for Contraindications Lesson 3:

Administration and Dosing

Lesson 4:

Follow-up Care and Side Effects
Assessment/Management

Flexible training resources for online, classroom-based, and hybrid learning

- Four self-paced digital lessons
- Downloadable job aids
- Adaptable resources for classroombased training
- Complementary mobile application for access to WHO guidance and interactive clinical tools

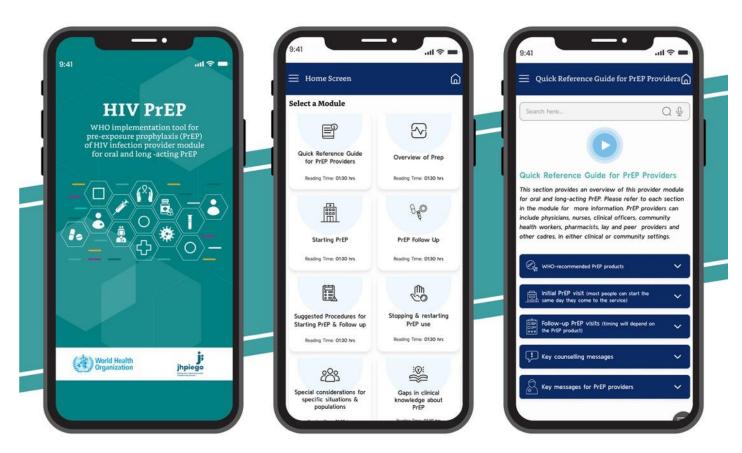
To learn more, scan or visit: www.jhpiego.org/HIVPrEPToolki



Mobile Application available for IOS and Android devices

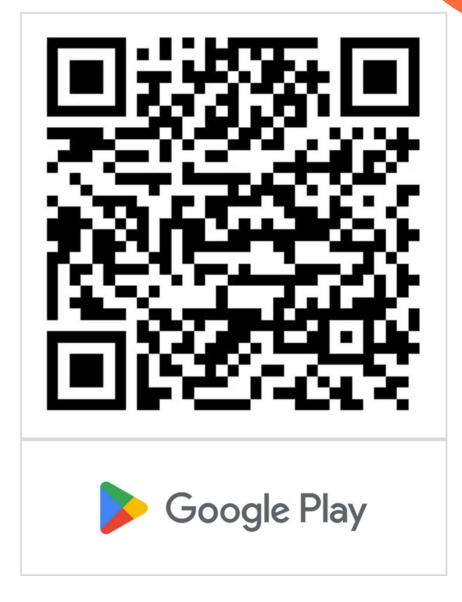
HIV PrEP Provider App

Empowering Providers to Deliver Oral & Long-Acting PrEP



Scan to download:





Question 1:

What is your role?

Healthcare Provider

Policymaker

Researcher

Program Manager/Administrator

Community health workers

Peers

Other



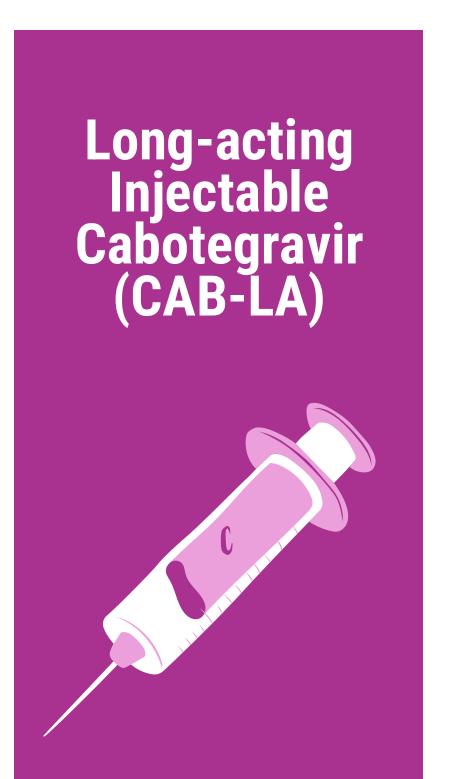
PrEP Overview

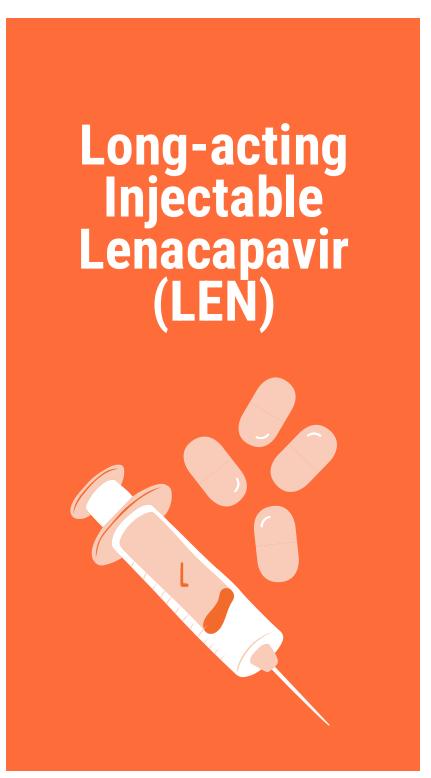
Michelle Rodolph, WHO

WHO recommended HIV PrEP Products:









Note: Not all PrEP products are available in all countries. Always refer to your national policies and guidelines to determine which HIV PrEP options are available locally.

Lenacapavir (LEN) for HIV prevention

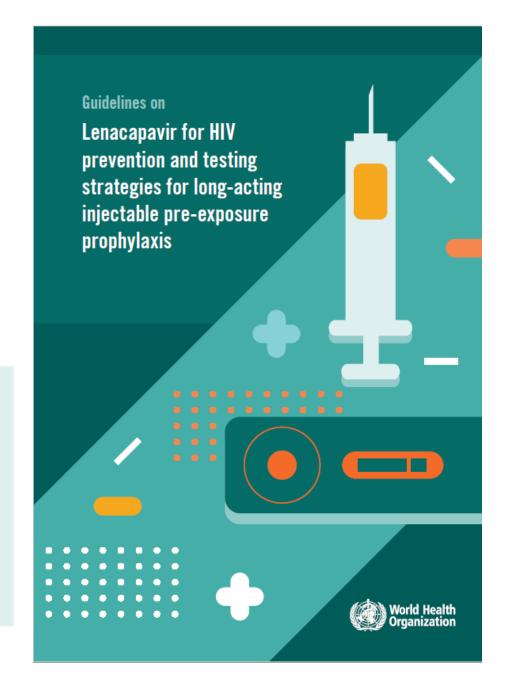
- Lenacapavir (LEN) is a first in class HIV-1 capsid inhibitor
 - Sub-cutaneous injectable formulation administered every 6 months, accompanied by an oral loading dose
 - Approved by US FDA in 2022 for treatment of multidrug resistant HIV in PLHIV who are highly treatment experienced, and in 2025 for HIV prevention

WHO Recommendation:



Recommendation [NEW]

Long-acting injectable lenacapavir should be offered as an additional prevention choice for people at risk of HIV, as part of combination prevention approaches. (strong recommendation, moderate to high certainty of evidence)





Long-acting Injectable Lenacapavir (LEN)



- LEN is manufactured and packaged in two different formulations:
 - a liquid solution injected subcutaneously
 - o an oral pill taken by mouth
- Clients take both oral pills AND injections to initiate LEN
- Once initiated, clients continue to receive injections every 6 months to stay protected

An HIV test is required to start and continue PrEP

Recommendation:

HIV self-testing may be used to deliver pre-exposure prophylaxis*, including for initiation, re-initiation and continuation (conditional recommendation, low-certainty evidence)

*Oral PrEP and the DVR



Recommendation [NEW]

Rapid diagnostic tests may be used for HIV testing for initiation, continuation and discontinuation of long-acting PrEP. (strong recommendation, very low certainty of evidence)



PrEP use in pregnancy and breastfeeding

- Oral PrEP, DVR, CAB-LA and LEN do NOT need to be discontinued during pregnancy and breastfeeding.
 - LEN showed no increase in adverse pregnancy or birth outcomes in the 193 pregnancies (among 184 women) reported in PURPOSE 1 so far.
 - No dose adjustment is likely to be required during pregnancy, with pharmacokinetic data indicating standard dosing remains effective.
- When someone becomes pregnant, the choice to start, continue, stop, or switch PrEP, should be made by the individual, following discussion of the risks and benefits with a health care provider.



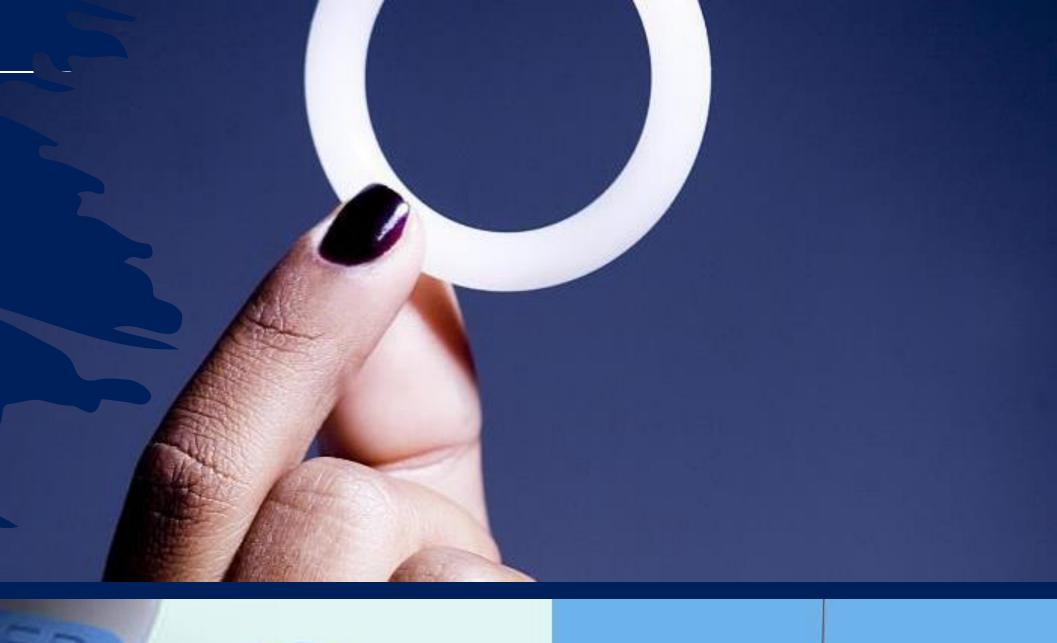


Offering <u>choice</u> in prevention and PrEP products can increase uptake, effective use, satisfaction and protection

- WHO does not support one PrEP product over any other
- Providers should explain the advantages, disadvantages and features of different options
- Different attributes may be more or less important for different people
- Choice is dynamic

The best PrEP product is the one someone wants to use and will use well







Case study

Elizabeth Irungu, Jhpiego Heather-Marie Schmidt, UNAIDS & WHO

Amina's Journey



Meet Amina

- Amina is a young woman.
- She is not married and does not know the HIV status of her partner.
- She has one child and is actively trying for another.
- She has no known illnesses.
- She has been using oral PrEP but is concerned about daily pill-taking, as she often forgets.
- She values privacy and wants fewer clinic visits.



Question 2:



Based on what you know, is Amina eligible for LEN?

Yes

No

Needs further evaluation

Answer: Needs further evaluation!

What steps are taken to assess whether a client is clinically eligible to start a PrEP product?

- Once the preferred PrEP product has been identified, providers must ensure the client is clinically eligible to start using it.
- There are multiple clinical assessment steps that should be completed to determine such eligibility.
- Some steps are common across all PrEP products, while others are product-specific.



Steps to Assess Clinical Eligibility

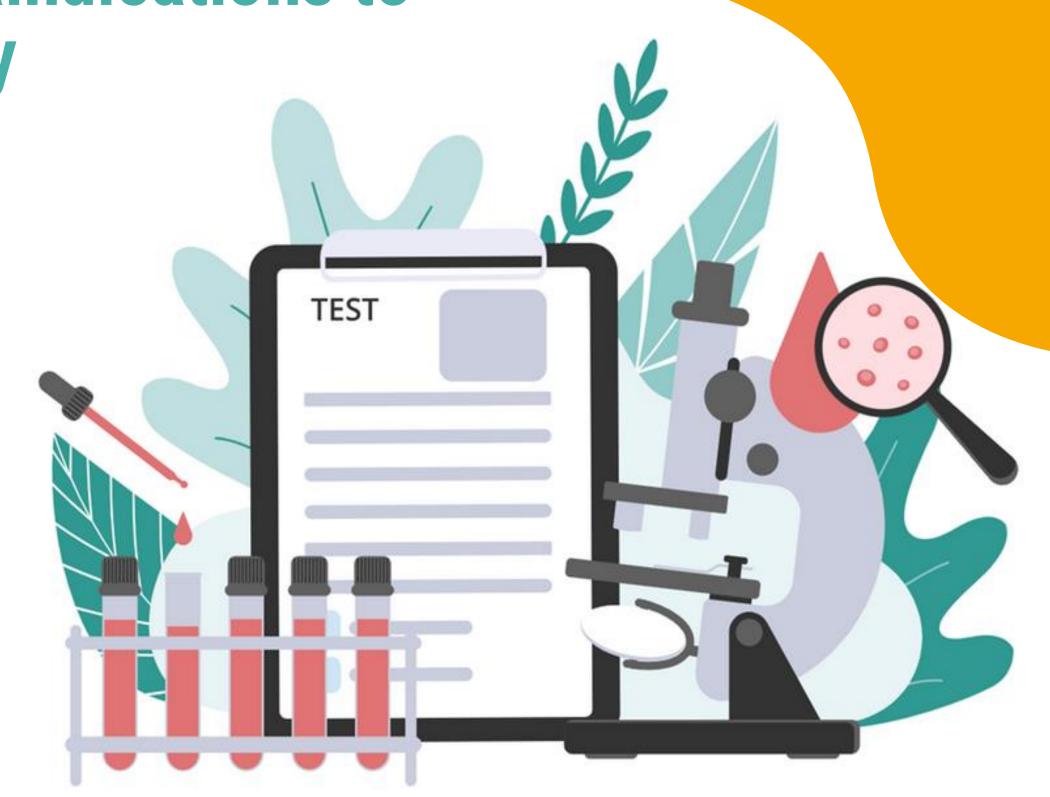
Providers should assess the following to determine eligibility for use of any PrEP product:

- 1 HIV Testing
- Possible exposure to HIV in the past 72 hours ("PEP Assessment")
- Signs/symptoms of acute HIV infection in past 2 weeks in the context of possible HIV exposure(s) in past 1 month ("AHI Assessment")
- Use of other medications or products that may interact with PrEP
- Medication allergies/hypersensitivities
- 6 Comorbidities

Your assessment of clinical eligibility will have revealed contraindications to PrEP use, if there are any

Use of any PrEP product is contraindicated in clients with:

- HIV or inconclusive HIV status
- High indication for PEP
- Allergic reaction to PrEP





In addition to the contraindications listed above for all PrEP products, the following contraindications and considerations to starting LEN also apply:

HIGH SUSPICION OF ACUTE HIV INFECTION

USE OF MEDICATIONS THAT INTERACT WITH LEN, WITH CONTRAINDICATIONS AND CONSIDERATIONS VARYING BY PRODUCT

RELEVANT COMORBIDITIES: NONE KNOWN



HIGH SUSPICION OF ACUTE HIV INFECTION

- If you have a high suspicion of AHI after assessing signs/symptoms and exposure history, advise the client to return in 1 month for HIV retesting. Further assessment of LEN eligibility should be deferred.
- The potential risks and benefits of deferring vs. starting LEN should be made on a caseby-case basis, with deferral chosen only when the risks of potentially starting LEN during AHI outweigh the benefits of using it to prevent HIV.
- Alternative HIV prevention strategies should be chosen while awaiting HIV retesting, which may include use of DVR, if available.

Reminder: Use of LEN by individuals living with HIV can result in development of viral drug resistance, whereby use of LEN or other capsid inhibitor drugs may be less effective at treating HIV in the future.



USE OF MEDICATIONS THAT INTERACT WITH LEN, WITH CONTRAINDICATIONS AND CONSIDERATIONS VARYING BY PRODUCT

There are few drug-drug interactions and contraindications to using LEN with other medications.

- There are differences between the regulatory labels for the US FDA (permits use with a dose adjustment) and EMA (contraindicated), regarding antibiotics used in the treatment of TB such as: Rifabutin, Rifampicin and Rifapentine.
- LEN is not expected to interact with gender-affirming hormones based upon the limited evidence available.

RELEVANT COMORBIDITIES: NONE KNOWN

There are no known comorbid conditions that contraindicate LEN use; therefore, no assessments of comorbidities are routinely necessary. It should be noted that individuals with severe hepatic impairment did not participate in LEN clinical trials.

PrEP Use in Pregnancy

- All PrEP products are considered by WHO to be **safe** and effective for use by pregnant and breastfeeding individuals, though evidence for dapivirine vaginal ring (DVR), CAB-LA, and lenacapavir (LEN) is more limited in comparison to TDF-based oral PrEP.
- In some countries, national regulatory bodies and policies may have additional guidance or contraindications for pregnancy or breastfeeding and for starting and/or continuing specific PrEP products, and pregnancy testing may be required in such locations.
- Providers should refer to the guidelines and policies in their country on this topic.





JOB AID: ASSESSMENT FOR PREP CLINICAL ELIGIBILITY AND CONTRAINDICATIONS





Assess the following	Clinical Contraindication or Special Consideration			
to determine if a client is clinically eligible for PrEP:	TDF-Based Oral PrEP	DVR 🔘	CAB-LA 📏	LEN 🥳
1) HIV Status	If HIV test results are positive or inconclusive, clients should be referred for further testing/treatment.	If HIV test results are positive or inconclusive, clients should be referred for further testing/treatment.	If HIV test results are positive or inconclusive, clients should be referred for further testing/treatment.	If HIV test results are positive or inconclusive, clients should be referred for further testing/treatment.
2) Post-Exposure Prophylaxis (PEP) Indication	If PEP is highly indicated, start client on 1 month course of PEP and defer/pause PrEP.	If PEP is highly indicated, start client on 1 month course of PEP and defer/pause PrEP.	If PEP is highly indicated, start client on 1 month course of PEP and defer/pause PrEP.	If PEP is highly indicated, start client on 1 month course of PEP and defer/pause PrEP.
3) Suspicion of Acute HIV Infection (AHI)	If high suspicion of AHI, defer/pause PrEP. Advise client to return in 1 month for re-testing	If high suspicion of AHI, proceed with eligibility screening and re-test in 1 month. DVR may be used despite suspicion of AHI	If high suspicion of AHI, defer/pause PrEP. Advise client to return in 1 month for re-testing	If high suspicion of AHI, defer/pause PrEP. Advise client to return in 1 month for re- testing
4) Possible Medication Interactions	Contraindications: TDF-based oral PrEP is not contraindicated with most commonly used medicines Considerations: If client is taking estradiol-based hormones: only use TDF-based dosing regimen/schedule recommended for cisgender women, transgender women taking gender-affirming hormones, and transgender men	Contraindications: Do not use in combination with contraceptive vaginal rings or diaphragms; avoid use with vaginally administered metronidazole or clindamycin Considerations: Concomitant use of vaginally administered clotrimazole should be with caution Offer condoms if concomitantly used with vaginally administered miconazole	Contraindications: Do not use in combination with: rifampin oxcarbazepine rifapentine phenobarbital carbamazepine phenytoin Considerations: Use in combination with rifabutin may require a dose adjustment, and prescribers should review the regulatory labels of both medications when being prescribed for concomitant use	Contraindications: There are no known medications contraindicated with LEN Considerations: Use of any of the following medications concomitantly with LEN or in the months after LEN discontinuation may require a dose adjustment (to the dose of either LEN or the other medication): Rifabutin Phenytoin Rifampicin Ketamine Rifapentine Avanafil Carbamazepine Sildenafil Phenobarbital Tadalafil Vardenafil
5) Possible Medication Allergies	If client has had previous allergic reaction to TDF, FTC or 3TC-based medications, recommend an alternative PrEP product	If client has had previous allergic reaction to DVR, recommend an alternative PrEP product	If client has had previous allergic reaction to cabotegravir, recommend an alternative PrEP product	If client has had previous allergic reaction to lenacapavir, recommend an alternative PrEP product
6) Relevant comorbidities	If client has impaired Renal Function (CrCI< 60 ml/min or eGFR 60 ml/min per 1.73 m2), recommend an alternative PrEP product	If client has severe vaginal health problems, treat before starting or continuing with DVR.	If client is known to have impaired liver function (i.e. chronic liver disease or acute hepatitis) recommend an alternative PrEP product	There are no known comorbidities that require assessment
	Note: renal function testing optional if client <49 years and free of renal comorbidities	Note: speculum examination is not required	Note: testing for viral hepatitis or liver function is not required prior to starting CAB-LA	

Amina's Eligibility

- After counseling, Amina and her provider decide that Lenacapavir could be a good choice for her, if she is clinically eligible
- She tests HIV negative and has no indication of PEP or suspicion of AHI.
- She is taking oral PrEP but no other medications
- She has not had any allergic reactions to PrEP in the past



Amina is eligible for Lenacapavir!



Question 3:

How do you initiate Amina on LEN?

2 injections today

2 oral pills today

1 injection today, 1 pill tomorrow

2 injections today, 2 pills today & 2 pills tomorrow

1 injection today, 1 pill today, & 1 pill tomorrow



Answer: 2 injections and 2 pills today 2 pills tomorrow



Starting LEN

- Starting LEN requires multiple doses of both oral and injectable LEN which we refer to collectively as the "INITIATION REGIMEN."
- The INTIATION REGIMEN must be administered for LEN to reach adequate drug levels in a timely manner.
- There should be no deviations from the INITIATION REGIMEN dosing specifications.
 Deviations may result in suboptimal protection against HIV, such as delays to onset of protection.





LEN Initiation Regimen

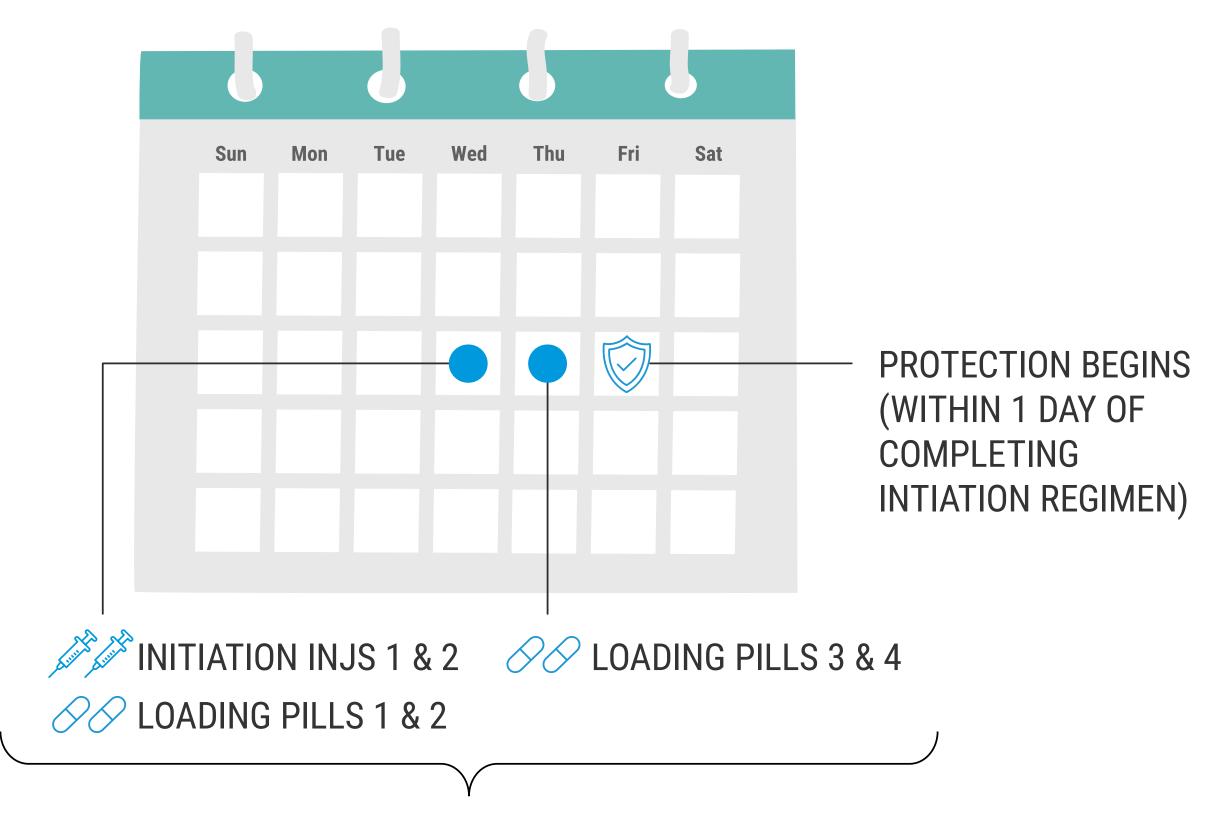


- Provider administers 2 LEN injections (INITIATION INJECTION 1 & INITIATION INJECTION 2)
- Client takes 2 LEN pills (LOADING PILLS 1 & 2) by mouth, and is provided with LOADING PILLS 3 & 4 to carry home



 Client takes 2 LEN pills (LOADING PILLS 3 & 4) by mouth

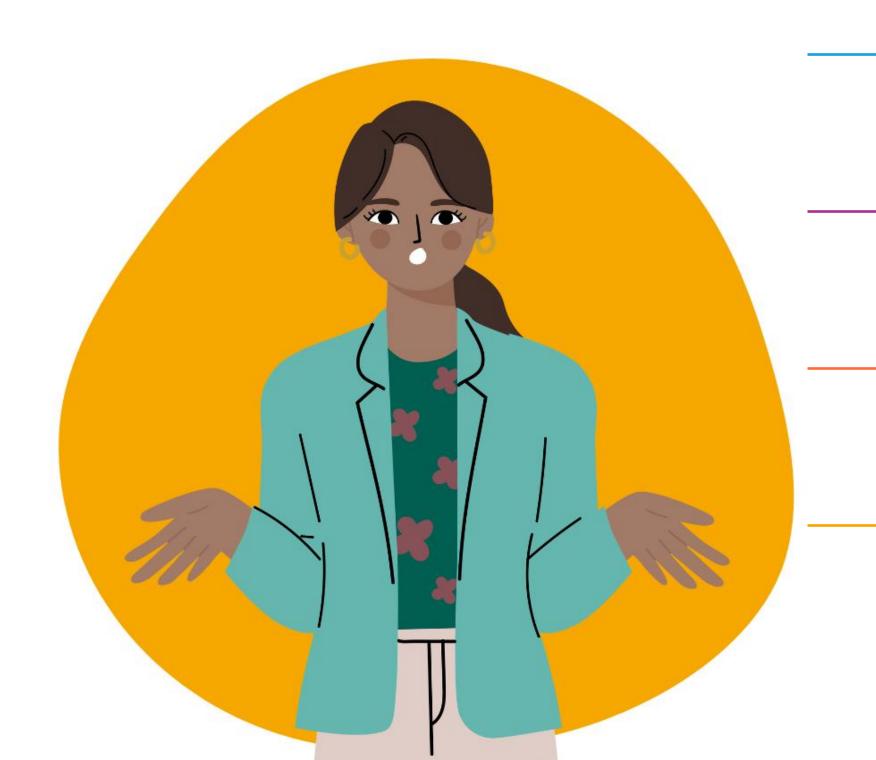
LEN STARTING MONTH



INITIATION REGIMEN

Question 4:

You have given Amina the INITIATION REGIMEN today, when should Amina return?



1 month from today

3 months from today

6 months from today

1 year from today

Answer: 6 months from today

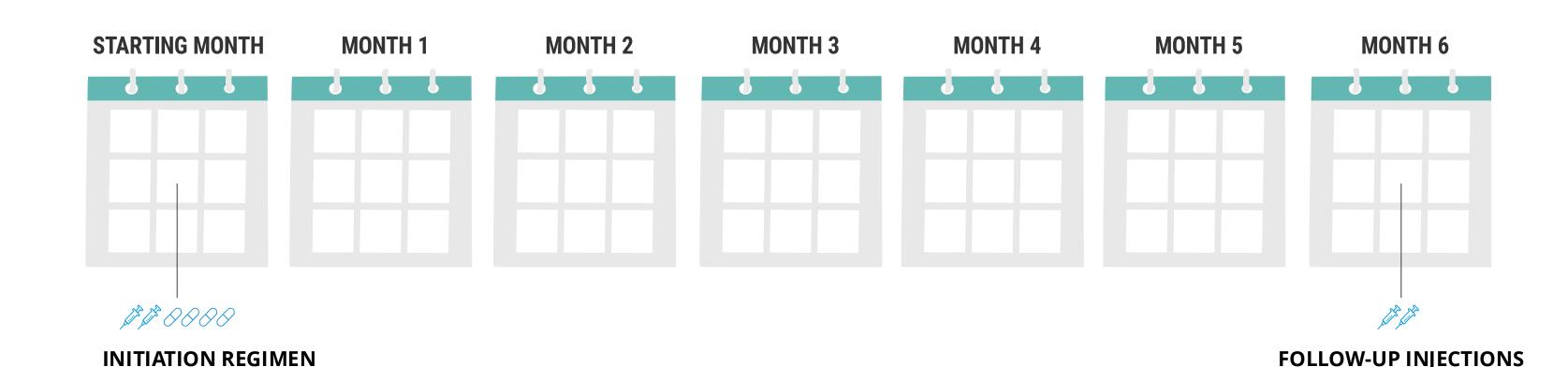


(INITIATION INJECTIONS 1&2/ LOADING PILLS 1-4)

Continuing LEN

After starting LEN by the INITIATION REGIMEN, subsequent **LEN injections are necessary every six months (26 weeks)** for those wanting to sustain protection. We refer to these biannual injections as FOLLOW-UP INJECTIONS.

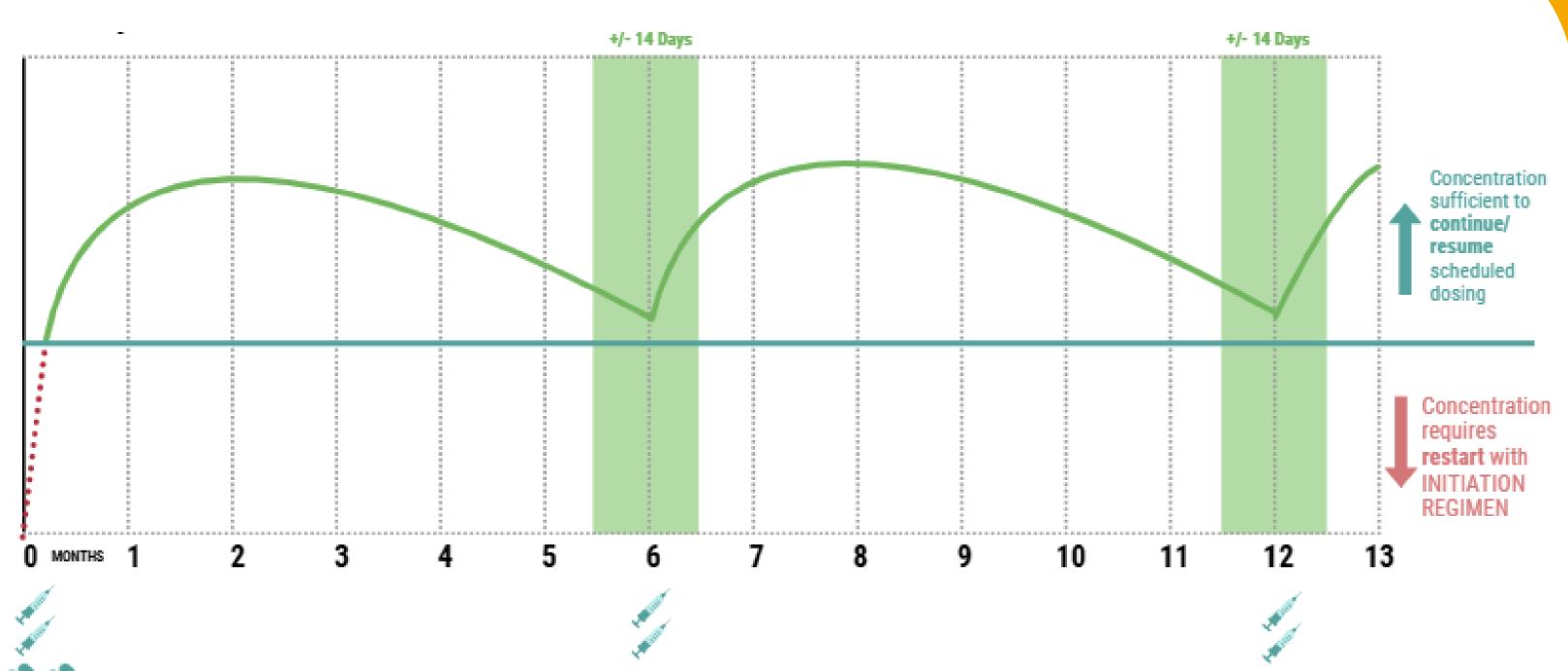
There is a +/- 14 day scheduling window for all FOLLOW-UP INJECTIONS.



6 MONTHS (26 WEEKS) +/- 14 DAYS



LEN Concentration in clients who return for on-time injections



Amina Misses her Appointment

- Amina started on LEN on April 1st and was scheduled to return (26 weeks later) on September 30th.
- She misses her appointment and returns to the clinic today (October 8)



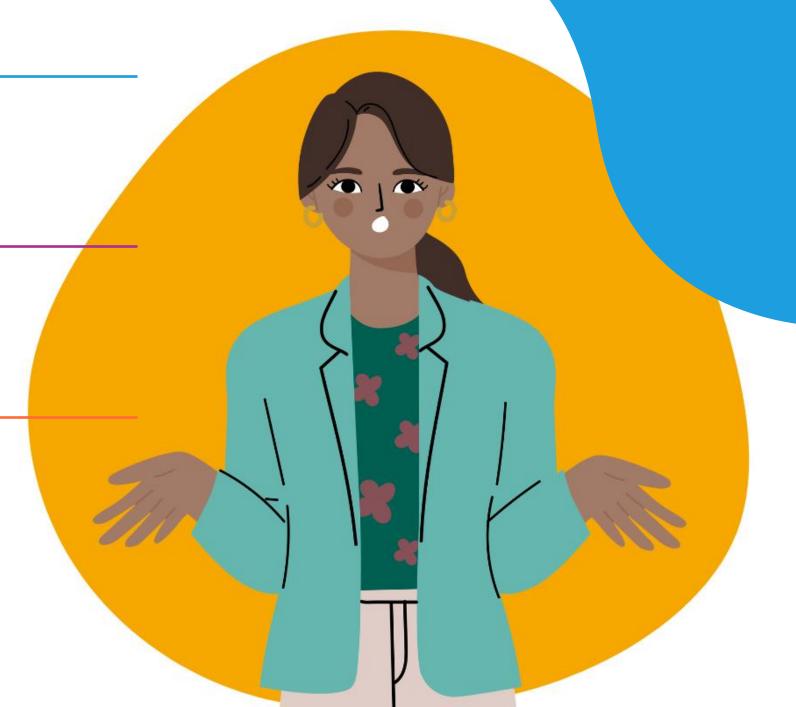
Question 5:

What should you do during Amina's visit today?

Resume with her follow-up LEN injections

Restart with LEN Initiation Regimen

Encourage her to switch to another PrEP method



Answer: RESUME with LEN Follow-Up Injections



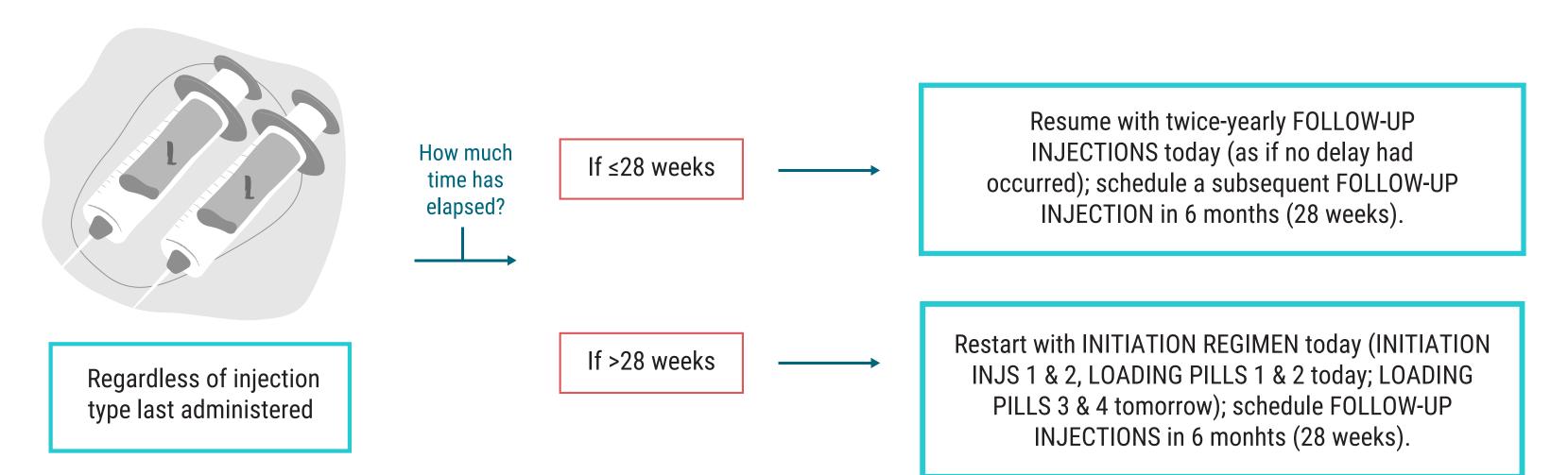
Missed Injections: LEN

- If a client misses a scheduled injection and wants to continue LEN, they should return to the site as soon as they are able
- The provider needs to make a decision whether to
 - Restart LEN with the INITIATION REGIMEN
 - Resume by administering FOLLOW-UP INJECTIONS



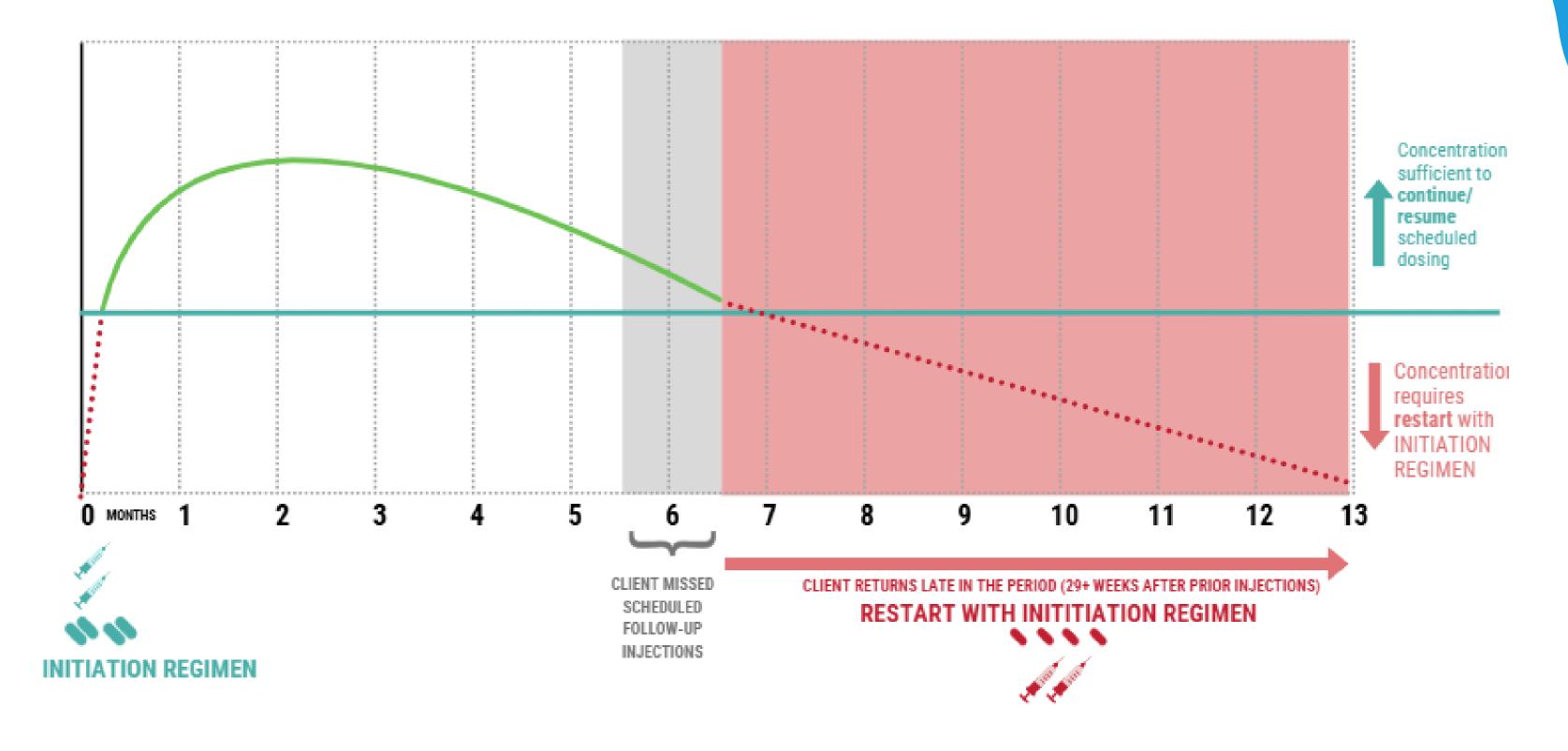
Missed LEN Injections

- The amount of time elapsed since their last injection will determine how to proceed, as follows:
 - o If ≤ 28 weeks (6 months plus 2 weeks) elapsed since prior injection, resume with bi-annual Follow-up Injection today; schedule a subsequent Follow-Up Injection in 6 months
 - If > 28 weeks elapsed since prior injection, restart with all LEN Loading Doses over two days (Loading Injections 1 & 2 and Loading Pills 1 & 2).





Concentration of Lenacapavir following Missed Injections





Amina's missed appointment

	APRIL						25
	S	т	F	s			
LEN INIT	ΓΙΑΤΙ	ON	1	2	3	4	5
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	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30			

M	ΑY				20	25
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11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

JUNE					20	25
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15	16	17	18	19	20	21
22	23	24	25	26	27	28
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JU	ILY			20	25	
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SEPTEMBER 2025										
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Amina returns 27 weeks + 1 day after her last injections.

RESUME with follow-up injections

Amina Misses her Appointment

- Amina started on LEN on April 1st and was scheduled to return (26 weeks later) on September 30th.
- She misses her appointment and returns to the clinic on **October 30**.



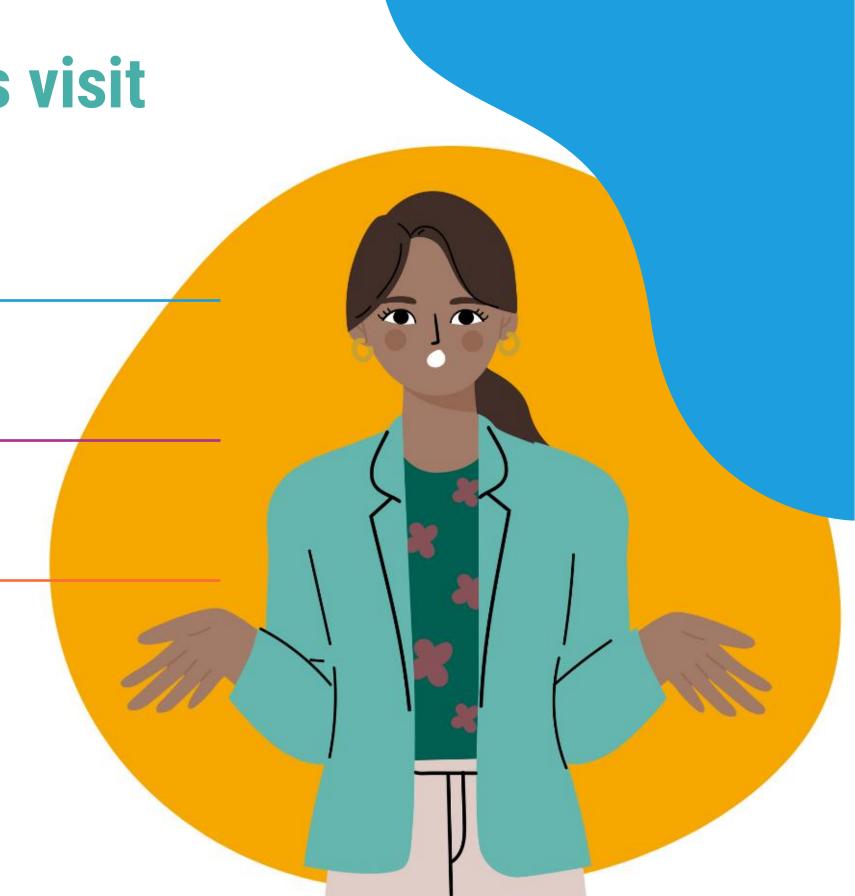
Question 6:

What should you do during Amina's visit on October 30th?

Resume with her follow-up LEN injections

Restart with LEN Initiation Regimen

Encourage her to switch to another PrEP method



ANSWER: RESTART with INITIATION REGIMEN



Amina's missed appointment

	APRIL					20	25
_	S	М	w	т	F	S	
LEN	INITIAT	ION	1	2	3	4	5
	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30			

M	ΑY				20	25	
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25	26	27	28	29	30	31	

JUNE 2025							
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AUGUST					20	25
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SEPTEMBER					20	25	
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21	22	23	24	25	26	27	
28	29	30	MISSED VISIT				

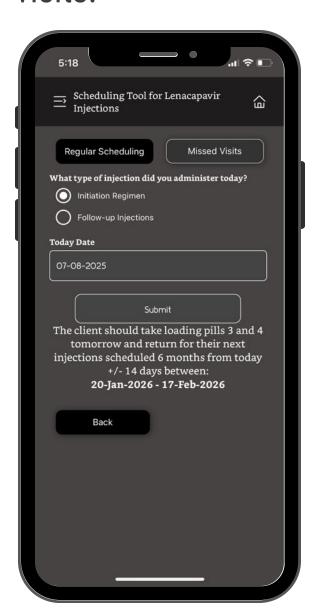
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S	М	т	w	т	F	S	
			1	2	3	4	
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19	20	21	22	23	24	25	
26	27	28	29	30	31		

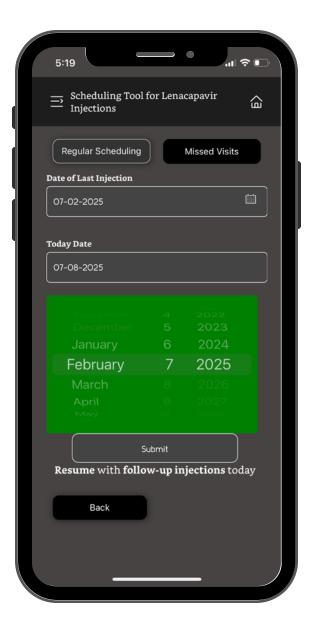
Amina returns 30 weeks + 2 days after her last injections.

RESTART with INITIATION REGIMEN

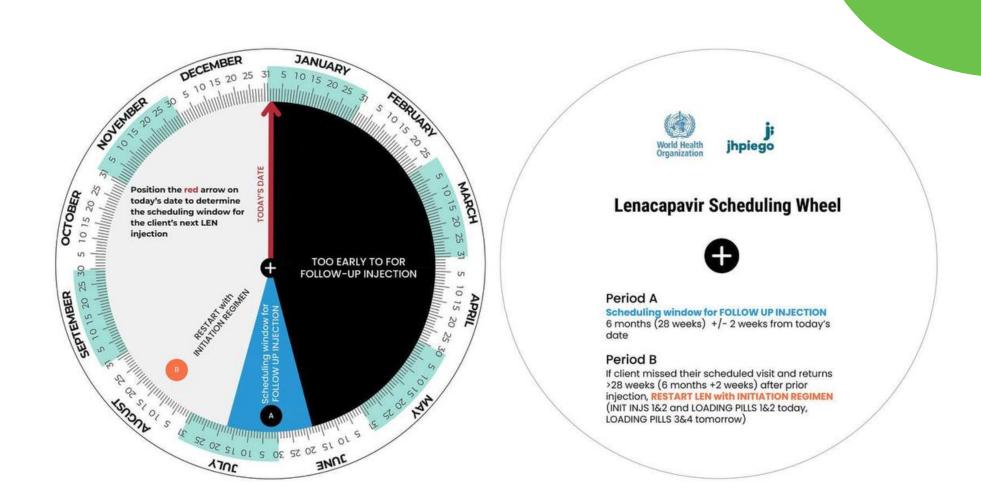
Available Resources on Scheduling

HIV PrEP Provider Application includes interactive digital scheduling tool for routine and missed visits.



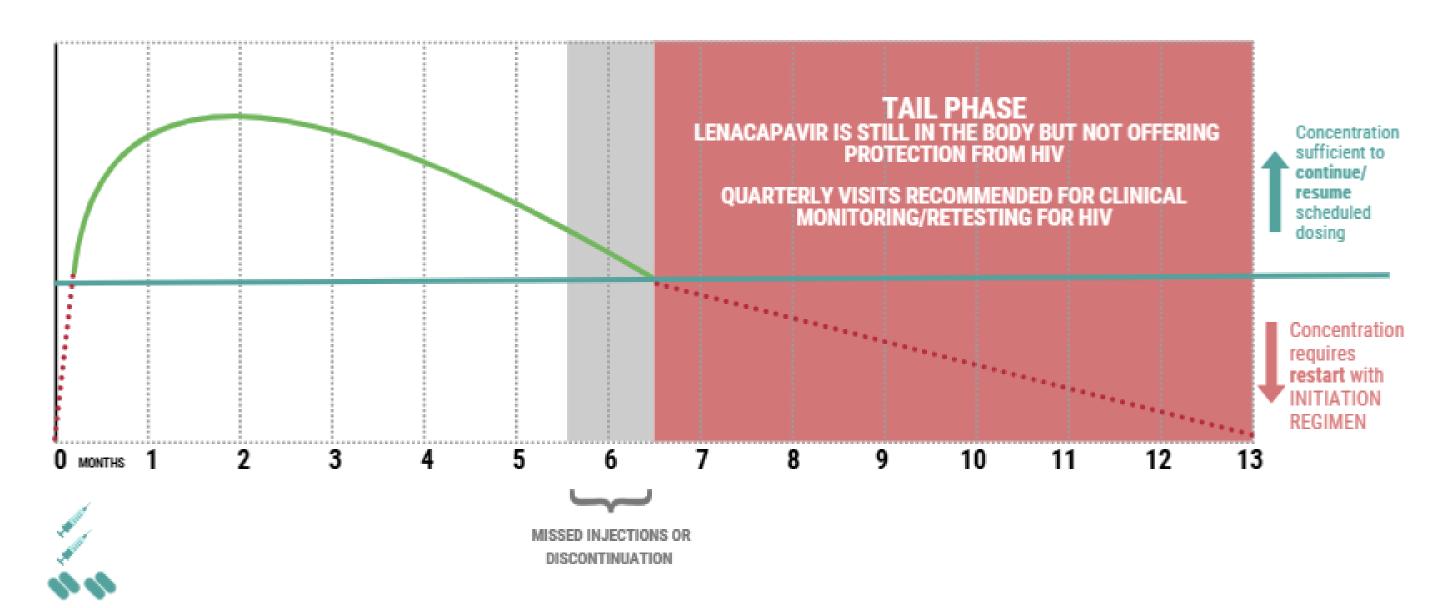


Printable Scheduling Wheels are available to assist in scheduling routine appointments and managing missed visits for LEN.



After Final LEN Injections

- LEN continues to provide protection for 6 months after the last injection.
- After a LEN injection (regardless of injection type), lenacapavir remains in the body for approximately 1 year, often referred to as the "tail."
- Drug levels are only protective for the first 6 months of the tail phase. For the 6 remaining months of the tail, lenacapavir levels are too low to provide protection.



Transitioning Between Products

What special considerations should be made for clients wishing to transition from using one PrEP product to another?

- Clients starting a particular PrEP product may decide later to switch to another option, for any number of reasons that may be related to their preferences or product characteristics.
- Considerations should be made to manage switching between PrEP products and maintaining continuity of HIV protection through overlapped use.
- For example, because the new PrEP product will not begin to protect against HIV immediately, it should be started before the prior PrEP product stops providing protection.



Question 7:

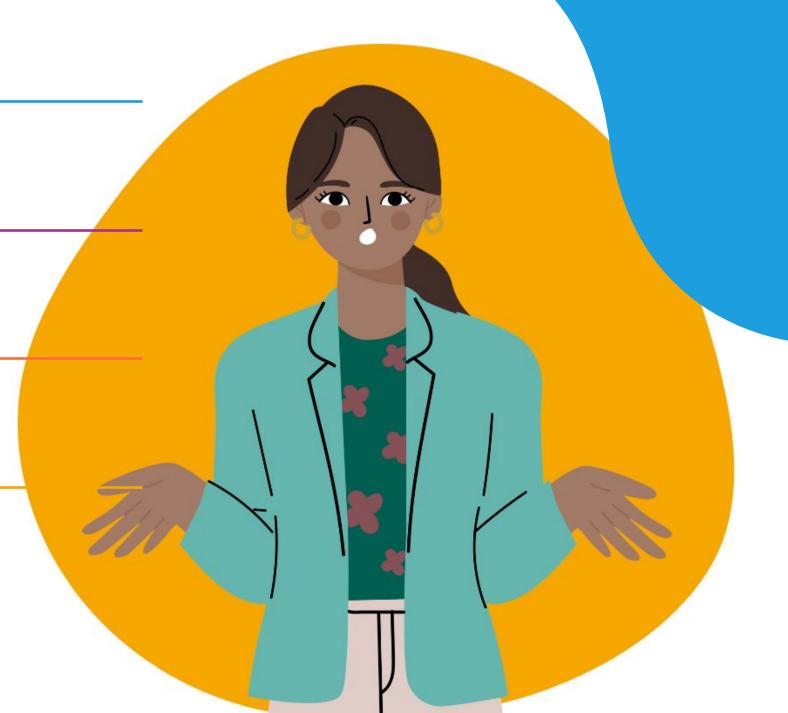
If Amina is already using oral PrEP, how should you manage her transition from oral PrEP to LEN?

Stop taking oral PrEP the day before initiating LEN

Stop taking oral PrEP the day Amina initiates LEN

Continue taking oral PrEP for the 2 days of LEN Initiation

Continue taking oral PrEP for 1 week after initiating LEN



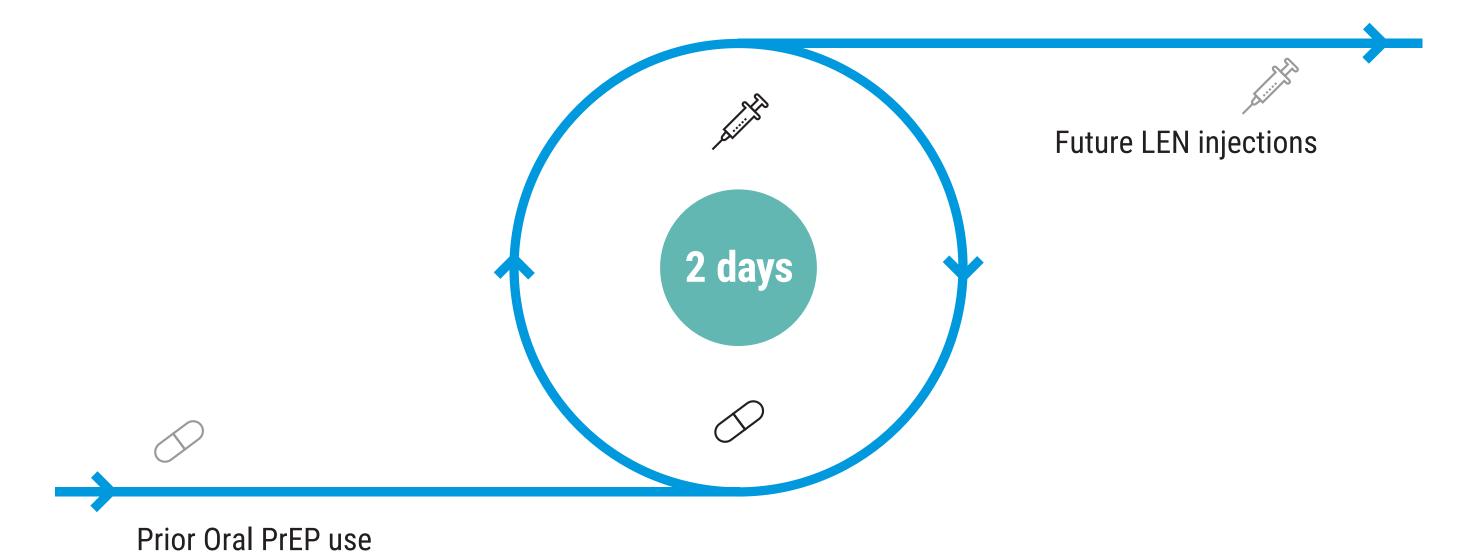
Answer: Continue taking oral PrEP for 2 days after initiating LEN

Switching from Oral PrEP - To LEN

Clients should continue using TDF-based oral PrEP throughout both days of receiving INITIATION REGIMEN to start LEN (all doses).

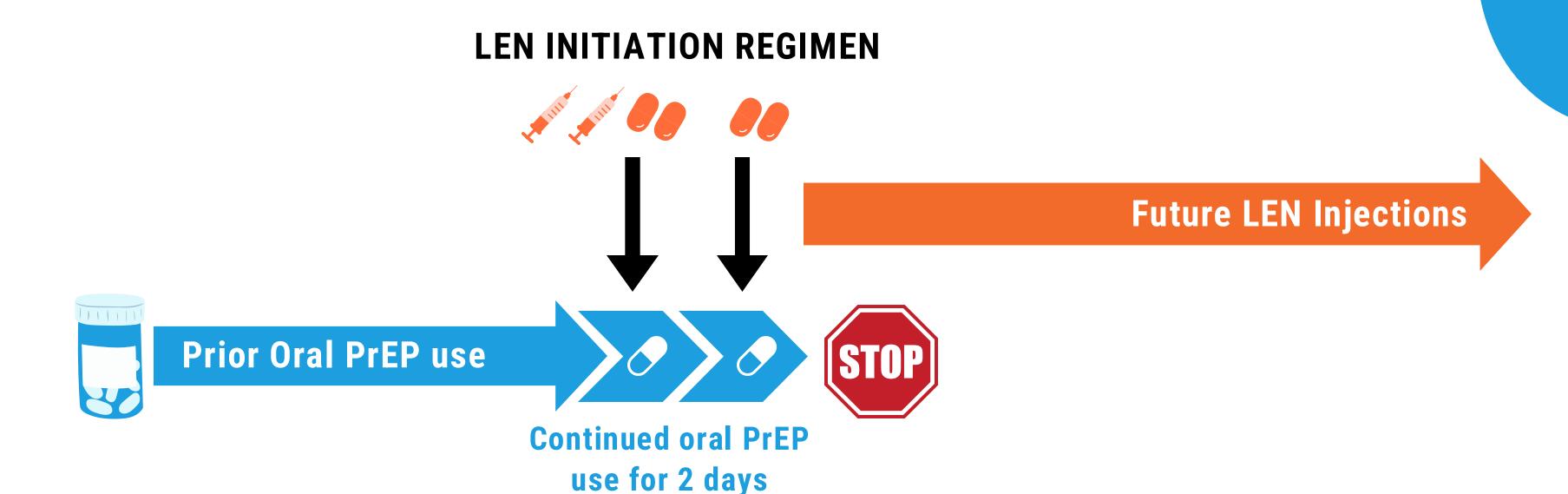
Transition Period:

2 days of continued oral TDF-based PrEP use after starting LEN



Switching from Oral PrEP - To LEN

Clients should continue using TDF-based oral PrEP throughout both days of receiving INITIATION REGIMEN to start LEN (all doses).



Switching From CAB-LA - To LEN

Clients should start the LEN INITIATION REGIMEN 1 month after INITIATION INJECTION 1 to ensure continued coverage.

Clients should start the LEN INITIATION REGIMEN 2 months after INITIATION INJECTION 2 or FOLLOW-UP INJECTION to ensure continued coverage.

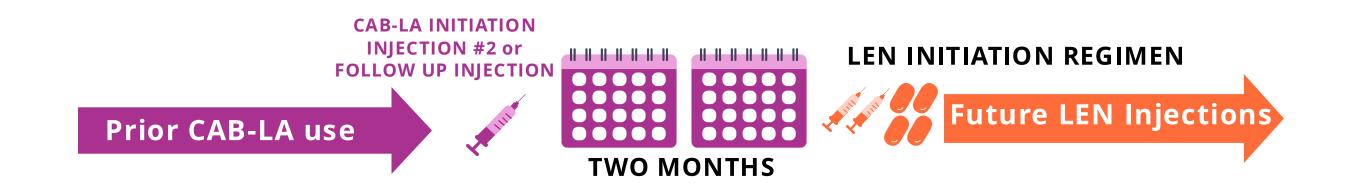
Transition Period: DVR, oral PrEP or LEN started within period when CAB-LA INIT INJ #1 still protective Start DVR, oral PrEP or LEN 1 month after INITIATION INJECTION #1 If last CAB-LA injection was INITIATION INJECTION #2 or FOLLOW-UP INJECTION

Switching From CAB-LA - To LEN

Clients should start the LEN INITIATION REGIMEN 1 month after INITIATION INJECTION 1 to ensure continued coverage.

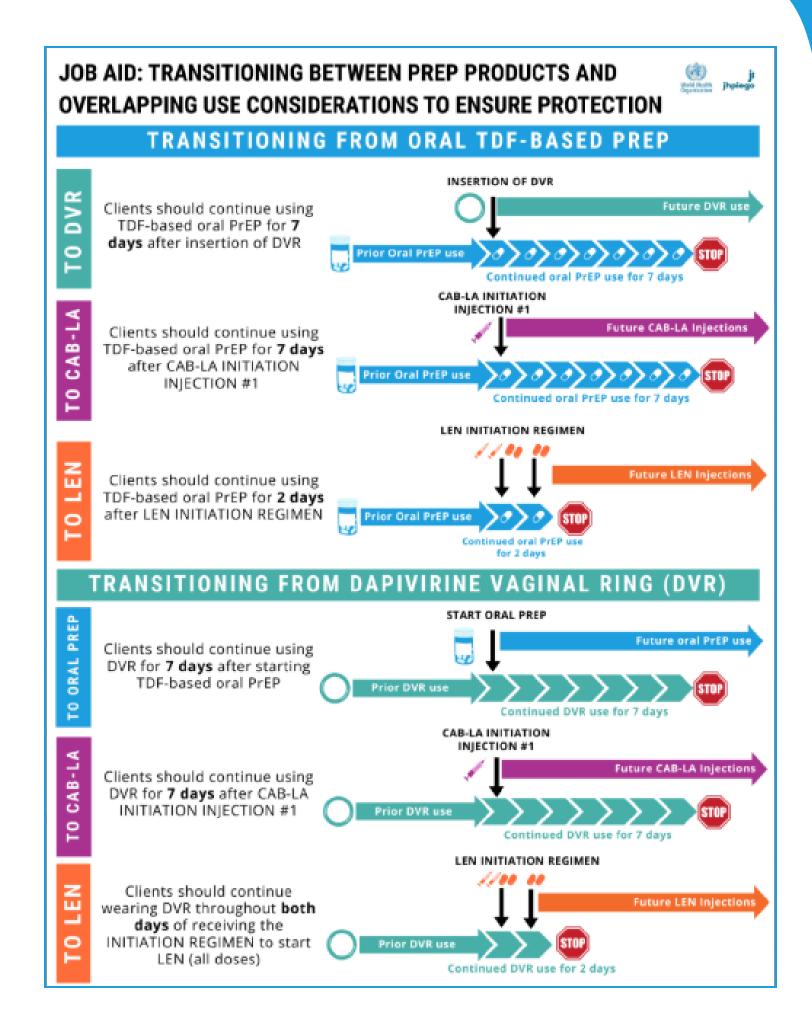


Clients should start the LEN INITIATION REGIMEN 2 months after INITIATION INJECTION 2 or FOLLOW-UP INJECTION to ensure continued coverage.



DOWNLOADABLE RESOURCES

Transitioning Between PrEP Products



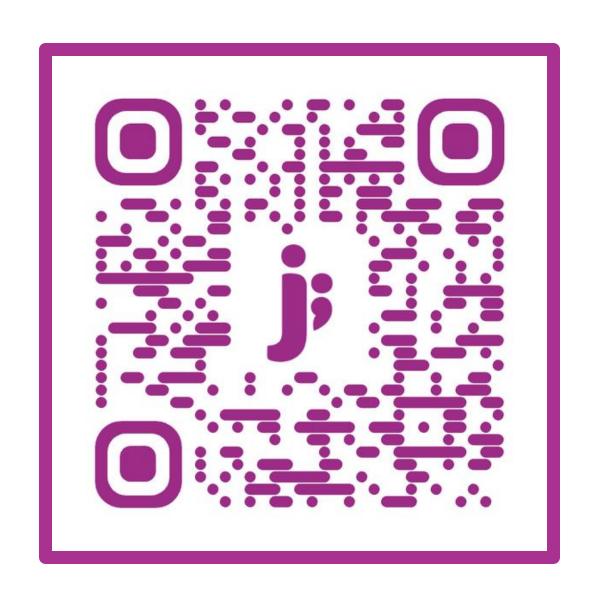
Adapting the toolkit

Jhpiego

How to use the Jhpiego/WHO PrEP Training Toolkit

All resources can be found on www.jhpiego.org/HIVPrEPToolkit

- Each lesson has a link for digital learning
- Open Google Drive Folder hosts all classroom-based learning materials
 - Job Aids
 - Downloadable and Editable PowerPoints for in-person or hybrid training
- Contact us (info@jhpiego.org) for direct access to digital files to utilize on national LMIS systems



COMING SOON: Lenacapavir-focused Learning Pathway!

Potential Adaptations for Lenacapavir Rollout

If planning national training for rollout of Lenacapavir, consider potential adaptations for classroom-based PowerPoints, including:

- Streamline content to focus on available HIV PrEP products in your country (remove products as needed)
- Review clinical eligibility according to your national guidelines, add any additional considerations
 - Consider: Age, pregnancy, etc.
- Add training details related to your country's national HIV testing guidelines
- Determine how to support providers in appointment scheduling (use of digital application, printable scheduling wheels, and/or paper-based calendars)
- Select the best format for upcoming trainings: virtual, in-person, or hybrid.

Feel free to contact our team with questions or support for utilizing the training toolkit!

Q+A

Moderator: Michelle Rodolph, WHO



Thank you!

For more information, visit: www.jhpiego.org/HIVPrEPtoolki t

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