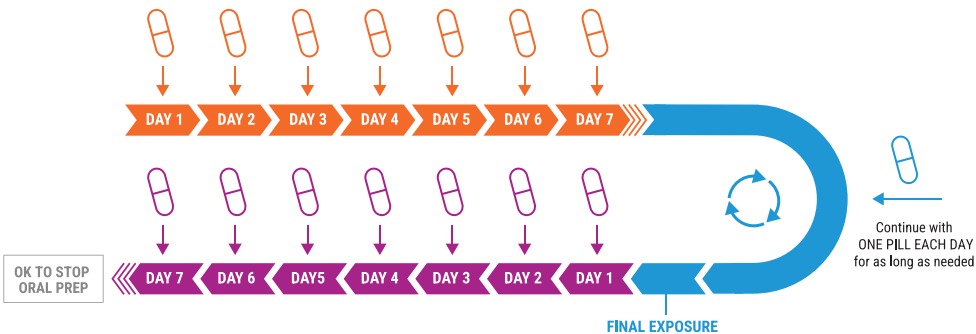


JOB AID: ASSESSING ORAL PREP USE DEVIATION SIGNIFICANCE AT FOLLOW-UP

GROUP A: cis-gender women, transgender women taking gender-affirming hormones, transgender men, and anyone using oral PrEP to prevent HIV from injecting practices

RECOMMENDED DOSING

- To start: 1 pill/day for at least 7 consecutive days prior to exposure
- While continuing: 1 pill/day for as long as protection is desired
- To stop: 1 pill/day for at least 7 consecutive days after the last potential exposure



PEP ASSESSMENT

IF CLIENT HAS HAD POSSIBLE EXPOSURE TO HIV IN THE PAST 72 HOURS

The period of interest when assessing for missed doses of oral PrEP is approximately 1-1.5 weeks (8-11 days) coinciding with the exposure event, as follows:

- In the 7 days before the possible high-risk exposure event
- The day of the exposure
- In the days transpired since the exposure (up to 3 days), which may include the PEP assessment date

FIGURE: FOR EACH EXPOSURE OCCURRING WITHIN PRIOR 72 HOURS OF ASSESSMENT

Use Evaluation Period (days)	1	2	3	4	5	6	7	8	9	10	11
Day # Relative to Exposure Event Date	Day -7	Day -6	Day -5	Day -4	Day -3	Day -2	Day -1	High-risk Exposure	1	2	3
Dose Taken or Missed Each Day	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗

AHI ASSESSMENT

IF CLIENT HAS AHI SIGNS/SYMPTOMS IN THE PAST 2 WEEKS AND POSSIBLE EXPOSURE TO HIV IN THE PAST MONTH

The period of interest when assessing for missed doses of oral PrEP is approximately 1-2 weeks (8-15 days) coinciding with each and every exposure event occurring in the prior month, as follows (and in the figure below):

- In the 7 days before each and every possible high-risk exposure event in the prior month
- The day(s) of the exposure(s) in the prior month
- In the days after each and every possible exposure (up to 7 days after each exposure) in the prior month, which may include the AHI assessment date

FIGURE: FOR EACH AND EVERY EXPOSURE OCCURRING THROUGHOUT PRIOR 1 MONTH

Use Evaluation Period (days)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Day # Relative to Exposure Event Date	Day -7	Day -6	Day -5	Day -4	Day -3	Day -2	Day -1	High-risk Exposure	1	2	3	4	5	6	7
Dose Taken or Missed Each Day	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗

What constitutes a significant use deviation?

There is no absolute rule about the number and pattern of missed doses that constitutes a significant use deviation. For clients, missing a single dose in the relevant period is usually not significant. However, missing multiple doses may constitute a significant use deviation for anyone, especially if doses were missed on consecutive days. Providers will need to made decisions on a case-by-case basis, taking into considerations all of the relevant details in order to determine whether the missed doses were significant.

## GROUP B:

cis-gender men, transgender women not taking gender-affirming hormones using oral PrEP to prevent HIV from injecting practices

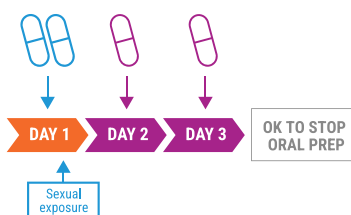
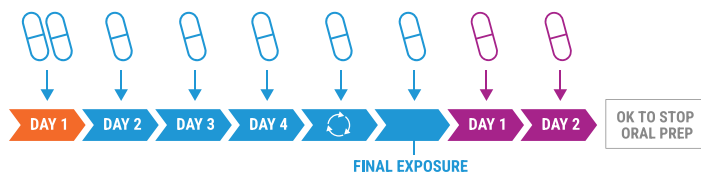
### RECOMMENDED DOSING

**To start:** 2 pill loading dose **2-24 hours before sex**

**While continuing:** 1 pill/day for as long as protection is desired

**To stop:** 1 pill/day for at least 2 consecutive days **after** the last potential sexual exposure

*Note: clients in this group have the option of event-driven dosing for one-off sexual exposure events (e.g. event-driven or 2+1+1 PrEP)*



### IF CLIENT HAS HAD POSSIBLE EXPOSURE TO HIV IN THE PAST 72 HOURS

The period of interest when assessing for missed doses of oral PrEP is approximately 0.5-1 week (3-5 days) coinciding with the exposure event, as follows:

- In the 2 days before the possible high-risk exposure event\*
- The day of the exposure
- In the days transpired since the exposure (up to 2 days), which may include the PEP assessment date

FIGURE: FOR EACH EXPOSURE OCCURRING WITHIN PRIOR 72 HOURS OF ASSESSMENT

Use Evaluation Period (days)	1	2	3	4	5	
Day # Relative to Exposure Event Date	Day -2	Day -1	High-risk Exposure	1	2	3
Dose Taken or Missed Each Day	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	

\*If the client use 2-pill loading dose to start event-driven regimen, assessment period is 2-24 hours before exposure (instead of 2 days before the exposure)

PEP ASSESSMENT

### IF CLIENT HAS AHI SIGNS/SYMPTOMS IN THE PAST 2 WEEKS AND POSSIBLE EXPOSURE TO HIV IN THE PAST MONTH

The period of interest when assessing for missed doses of oral PrEP is approximately 0.5-1 week (3-5 days) coinciding with *each and every exposure event occurring in the prior month*, as follows (and in the figure below):

- In the 2 days before each and every possible high-risk exposure event in the prior month
- The day(s) of the exposure(s) in the prior month
- In the days after each and every possible exposure (up to 2 days after each exposure) in the prior month, which may include the AHI assessment date

FIGURE: FOR EACH AND EVERY EXPOSURE OCCURRING THROUGHOUT PRIOR 1 MONTH

Total Duration (days)	1	2	3	4	5
Day # Relative to Exposure Event Date	Day -2	Day -1	High-risk Exposure	1	2
Dose Taken or Missed Each Day	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗	✓ or ✗

AHI ASSESSMENT

### What constitutes a significant use deviation?

There is no absolute rule about the number and pattern of missed doses that constitutes a significant use deviation. For Group B clients using event-driven/2+1+1 oral PrEP dosing missing even a single dose in the relevant period may be significant. For other clients, missing a single dose may not be significant. The more doses a client has taken, the less significant missing a single dose is. However, missing multiple doses may constitute a significant use deviation for anyone, especially if doses were missed on consecutive days. Providers will need to make decisions on a case-by-case basis, taking into consideration all of the relevant details in order to determine whether the missed doses were significant.

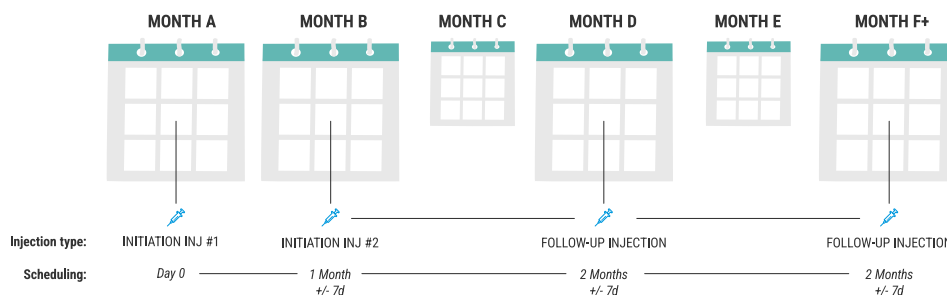
# JOB AID: ASSESSING LONG-ACTING CABOTEGRAVIR (CAB-LA)

## USE DEVIATION SIGNIFICANCE AT FOLLOW-UP

### RECOMMENDED DOSING

CAB-LA dosing should be as follows:

- The first two injections (INITIATION INJECTIONS 1 & 2) should be administered 1 month apart (+/- 7 days)
- All FOLLOW-UP INJECTIONS should be administered every 2 months (+/- 7 days)



### IF CLIENT HAS HAD POSSIBLE EXPOSURE TO HIV IN THE PAST 72 HOURS

After identifying a possible high-risk exposure in the past 72 hours in a returning CAB-LA client, providers must next assess for CAB-LA use deviation (delays in reinjection). For clients delayed in returning, the significance of the use deviation depends on duration since the last injection.

- For clients delayed in returning for **INITIATION INJECTION 2**, if more than **5 weeks (1 month +7 days)** have passed since INITIATION INJECTION 1, the deviation may be significant (see figure below).
- For clients delayed in returning for **FOLLOW-UP INJECTION**, if more than **9 weeks (2 months +7 days)** have passed since prior injection, the deviation may be significant (see figure below).

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **INITIATION INJECTION 2**

Time Since INITIATION INJECTION 1 (weeks)	1	2	3	4	5	6+
Exposure Event Protected?	-	✓	✓	✓	✓	✗

EXPOSURE EVENT IN PRIOR 72 HOURS  
LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION (AND  
LESS PROTECTION)

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **FOLLOW-UP INJECTION**

Time Since Prior Injection (INITIATION INJECTION 2 or FOLLOW-UP INJECTION) (weeks)	1	2	3	4	5	6	7	8	9	10+
Exposure Event Protected?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

EXPOSURE EVENT IN PRIOR 72 HOURS  
LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION  
(AND LESS PROTECTION)

### IF CLIENT HAS AHI SIGNS/SYMPTOMS IN THE PAST 2 WEEKS AND POSSIBLE EXPOSURE TO HIV IN THE PAST MONTH

In returning clients with AHI signs/symptoms in the past 2 weeks and possible exposure to HIV in the past month, providers must assess for CAB-LA use deviations, (delays in reinjections) For clients delayed in returning, the significance of the use deviation depends on the duration since the last injection

- For clients delayed in returning for **INITIATION INJECTION 2**, if more than **5 weeks (1 month +7 days)** have passed since INITIATION INJECTION 1, the deviation may be significant (see figure below).
- For clients delayed in returning for **FOLLOW-UP INJECTION**, if more than **9 weeks (2 months +7 days)** have passed since prior injection, the deviation may be significant (see figure below).

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **INITIATION INJECTION 2**

Time Since INITIATION INJECTION 1 (weeks)	1	2	3	4	5	6+
Exposure Event Protected?	-	✓	✓	✓	✓	✗

EACH AND EVERY EXPOSURE EVENT OCCURRING IN  
THIS PERIOD LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION (AND  
LESS PROTECTION)

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **FOLLOW-UP INJECTION**

Time Since Prior Injection (INITIATION INJECTION 2 or FOLLOW-UP INJECTION) (weeks)	1	2	3	4	5	6	7	8	9	10+
Exposure Event Protected?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

EACH AND EVERY EXPOSURE EVENT OCCURRING IN  
THIS PERIOD LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION  
(AND LESS PROTECTION)

### What constitutes a significant use deviation?

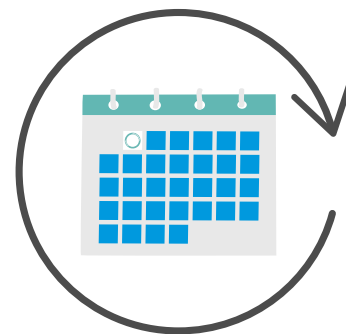
It is best if CAB-LA injections occur without any delay. Providers will need to make decisions on a case-by-case basis, taking into consideration all of the relevant details in order to determine whether a delayed reinjection was significant.

# JOB AID: ASSESSING DAPIVIRINE VAGINAL RING (DVR) USE DEVIATION SIGNIFICANCE AT FOLLOW-UP

## RECOMMENDED DOSING

DVR should be worn **continuously for 1 month after insertion** and only removed to replace with a new ring.

At a minimum, DVR should be inserted 24 hours before vaginal sex, worn during sex, and remain in place for at least a day after sex (though exact duration the ring needs to remain in place to protect against HIV is not known.)



### IF CLIENT HAS HAD POSSIBLE EXPOSURE TO HIV IN THE PAST 72 HOURS

After identifying a possible high-risk exposure in the past 72 hours in a returning DVR client, providers must next assess for DVR use deviations (days when DVR was not worn) and determine their significance. Non-use of DVR is most relevant in the **24 hours before the exposure event and the day of the exposure event**.

FIGURE: FOR EACH EXPOSURE OCCURRING WITHIN PRIOR 72 HOURS OF ASSESSMENT

Use Evaluation Period (days)	1	2	3	4	5
Time Relative to Exposure Event Date	Hours -24	High-risk Exposure			
DVR Worn Each Day?	✓ or ✗	✓ or ✗			

### IF CLIENT HAS AHI SIGNS/SYMPTOMS IN THE PAST 2 WEEKS AND POSSIBLE EXPOSURE TO HIV IN THE PAST MONTH

In returning clients with AHI signs/symptoms in the past 2 weeks and possible exposure to HIV in the past month, providers must assess for DVR use deviations, coinciding with **all such exposures** and determine their significance. Non-use of DVR is most relevant in the **24 hours before and the day of any possible exposure(s)** that occurred throughout the prior month

FIGURE: FOR EACH AND EVERY EXPOSURE OCCURRING THROUGHOUT PRIOR 1 MONTH

Total Duration (days)	1	2
Time Relative to Exposure Event Date	Hours -24	High-risk Exposure Date
DVR Worn Each Day?	✓ or ✗	✓ or ✗

### What constitutes a significant use deviation?

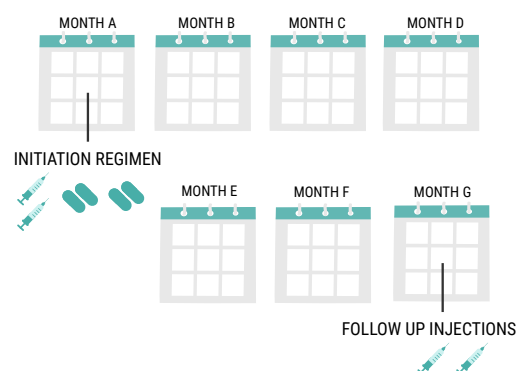
It is best if DVR was worn continuously and not removed except to replace it with a new one. Not wearing the DVR for the 24 hours before and the day after a possible exposure likely constitutes a significant use deviation. Providers will need to make decisions on a case-by-case basis, taking into considerations all of the relevant details in order to determine whether the days of not wearing DVR were significant.

# JOB AID: ASSESSING LENACAPAVIR USE DEVIATION SIGNIFICANCE AT FOLLOW-UP

## RECOMMENDED DOSING

LEN dosing should be as follows:

- The INITIATION REGIMEN consists of oral pills *and* injections
  - Day 0: Provide administers INITIATION INJECTION 1 and INITIATION INJECTION 2. Client takes 2 LEN pills (LOADING PILLS 1 & 2)
  - Day 1: client takes 2 LEN pills (LOADING PILLS 3 & 4)
- FOLLOW-UP INJECTIONS should be administered every 6 months (26 weeks) +/- 14 days



### IF CLIENT HAS HAD POSSIBLE EXPOSURE TO HIV IN THE PAST 72 HOURS

After identifying a possible high-risk exposure in the past 72 hours in a returning LEN client, providers must next assess for LEN use deviation (delays in follow-up injections). For clients delayed in returning, the significance of the use deviation depends on duration since the last injection.

- For clients delayed in returning for **FOLLOW-UP INJECTIONS**, if more than **28 weeks (6 months +14 days)** have passed since INITIATION REGIMEN or previous FOLLOW-UP INJECTION, the deviation may be significant (see figure below)

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **FOLLOW-UP INJECTIONS**

Time since previous injection (weeks)	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+
Exposure event protected?	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

EXPOSURE EVENT IN PRIOR 72 HOURS  
LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION (AND  
LESS PROTECTION)

### IF CLIENT HAS AHI SIGNS/SYMPTOMS IN THE PAST 2 WEEKS AND POSSIBLE EXPOSURE TO HIV IN THE PAST MONTH

In returning clients with AHI signs/symptoms in the past 2 weeks and possible exposure to HIV in the past month, providers must assess for LEN use deviations, (delays in reinjections). For clients delayed in returning, the significance of the use deviation depends on the duration since the last injection

- For clients delayed in returning for **FOLLOW-UP INJECTIONS**, if more than **28 weeks (6 months +14 days)** have passed since INITIATION REGIMEN or previous FOLLOW-UP INJECTION, the deviation may be significant (see figure below)

FIGURE: FOR CLIENTS DELAYED IN RETURNING FOR **FOLLOW-UP INJECTIONS**

Time since previous injection (weeks)	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+
Exposure event protected?	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

EACH AND EVERY EXPOSURE EVENT OCCURRING IN  
THIS PERIOD LIKELY NOT PROTECTED

GREATER DELAY EQUATES TO  
INCREASE OF USE DEVIATION (AND  
LESS PROTECTION)

## What constitutes a significant use deviation?

It is best if LEN injections occur without any delay. Providers will need to made decisions on a case-by-case basis, taking into considerations all of the relevant details in order to determine whether delayed reinjections were significant.

# JOB AID: PREP SIDE EFFECTS AND OTHER COMPLICATIONS

## TDF-BASED ORAL PrEP



- Possible side effects may include:
- GI symptoms (diarrhea, nausea, decreased appetite, cramping, flatulence)
  - Dizziness
  - Headaches

### MANAGEMENT

Side effects can often be managed symptomatically, usually with non-prescription medicines when indicated, and typically resolve within the first month without the need to stop oral PrEP. They tend to become milder over time. Clients should be advised to contact their provider if symptoms are severe or prolonged, or if they're concerned.

Mild	Reassure the client this is common and improves with time.
Moderate	Suggest treatment with non-prescription medication (i.e pain medication, non-steroidal anti-inflammatory drugs (NSAIDs), antipyretic, anti-emetics, or anti-diarrheals) to relieve symptoms <i>Note: Pregnant clients should avoid use of NSAIDs.</i>
Severe	Refer for further evaluation

## VAGINAL RING (DVR)



- Possible side effects may include:
- Urinary tract infection
  - Inflammation of the vagina, vulva or cervix
  - Vaginal discharge
  - Vaginal or vulvar itching
  - Pelvic or lower abdominal pain

### MANAGEMENT

Side effects can often be managed symptomatically, usually with non-prescription medicines when indicated, and typically resolve within the first month and without needing to remove the DVR.

Mild	Reassure the client this is common and improves with time.
Moderate	Suggest treatment with non-prescription medication (i.e. topical creams) to relieve symptoms
Severe	Refer for further evaluation

Clients should be advised to contact their provider if symptoms are severe or prolonged, or if they're concerned. Clients should be advised to return to the clinic immediately if they have any signs/symptoms of hypersensitivity, including: prolonged vomiting, shortness of breath, fever, and/or severe generalized rash (blistering, sores in the mouth)



LONG-ACTING CABOTEGRAVIR (CAB-LA)



- Possible side effects may include:
- Injection site reactions
    - Pain, Swelling, Nodules, Induration (thickening/hardening of tissue at injection site), Redness/bruising, Itching
  - Headache/ Dizziness
  - Nausea/ Diarrhea
  - Tiredness

MANAGEMENT

Of those listed, the most common side effects are injection site reactions, and these are more common with early injections and then usually decrease with subsequent injections.

Mild	Clients may use a warm or cold compress
Moderate	Suggest non-prescription pain medication or non-steroidal anti-inflammatory drugs (NSAIDs), which may be taken before as well as after injections to minimize pain and swelling, provided there is no contraindication to their use in the client. <i>Note: Pregnant clients should avoid use of NSAIDs.</i>
Severe	Refer for further evaluation, if fluctuant abscess is present and does not drain spontaneously, incision and drainage and antibiotics may be necessary

Other side effects can often be managed symptomatically, usually with non-prescription medicines when indicated, and typically resolve without the need to discontinue CAB-LA.

Mild	Reassure the client this is common and improves with time.
Moderate	Suggest treatment with non-prescription medication (i.e pain medication, non-steroidal anti-inflammatory drugs (NSAIDs), antipyretic, anti-emetics, or anti-diarrheals) to relieve symptoms <i>Note: Pregnant clients should avoid use of NSAIDs.</i>
Severe	Refer for further evaluation

Clients should be advised to contact their provider if symptoms are severe or prolonged, or if they’re concerned. Clients should be advised to return to the clinic immediately if they have any signs/symptoms of hypersensitivity, including: prolonged vomiting, shortness of breath, fever, and/or severe generalized rash (blistering, sores in the mouth)

LENACAPAVIR (LEN)



- Possible side effects may include:
- Injection site reactions
    - Pain, Swelling, Nodules, Induration (thickening/hardening of tissue at injection site), Redness/bruising, Itching
  - Headache
  - Nausea/ Diarrhea
  - Tiredness

MANAGEMENT

Of those listed, the most common side effects are injection site reactions, including nodules. Both nodules and indurations may resolve more slowly than other injection site reactions (several months to a year or more). Nodules may not be visible but may be easily felt.

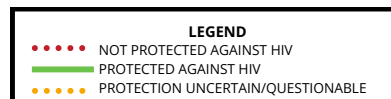
Mild	Clients may use ice/cold compress
Moderate	Suggest non-prescription pain medication or non-steroidal anti-inflammatory drugs (NSAIDs), which may be taken before as well as after injections to minimize pain and swelling, provided there is no contraindication to their use in the client. <i>Note: Pregnant clients should avoid use of NSAIDs.</i>
Severe	Refer for further evaluation

Other side effects can often be managed symptomatically, usually with non-prescription medicines when indicated, and typically resolve without the need to discontinue LEN.

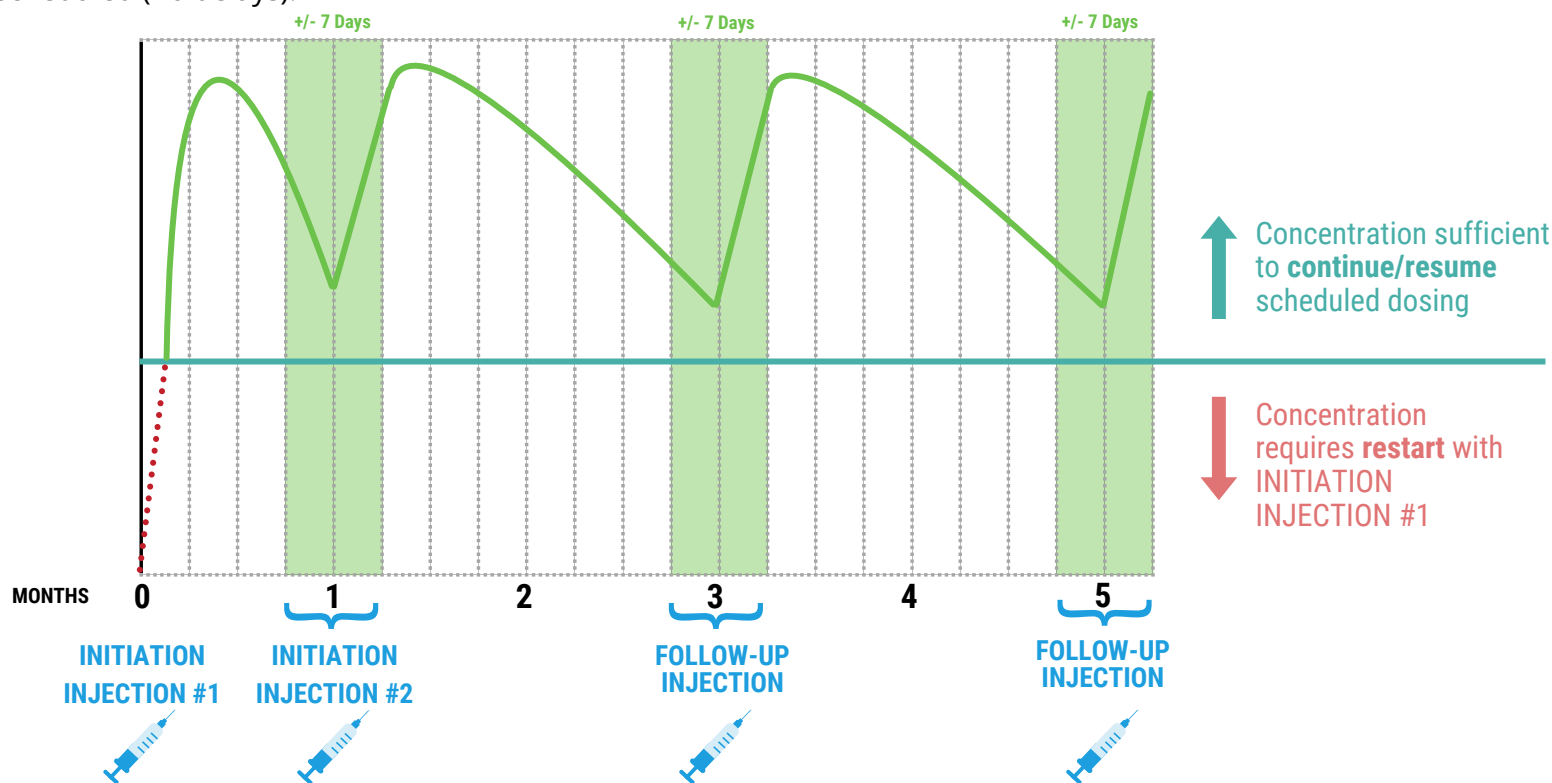
Mild	Reassure the client this is common and improves with time.
Moderate	Suggest treatment with non-prescription medication (i.e pain medication, non-steroidal anti-inflammatory drugs (NSAIDs), antipyretic, anti-emetics, or anti-diarrheals) to relieve symptoms <i>Note: Pregnant clients should avoid use of NSAIDs.</i>
Severe	Refer for further evaluation

# JOB AID: CAB CONCENTRATION CHANGE SCENARIOS

## CAB-LA SCENARIO 1: CAB-LA INITIATION AND ON-TIME RETURN FOR ALL REINJECTIONS

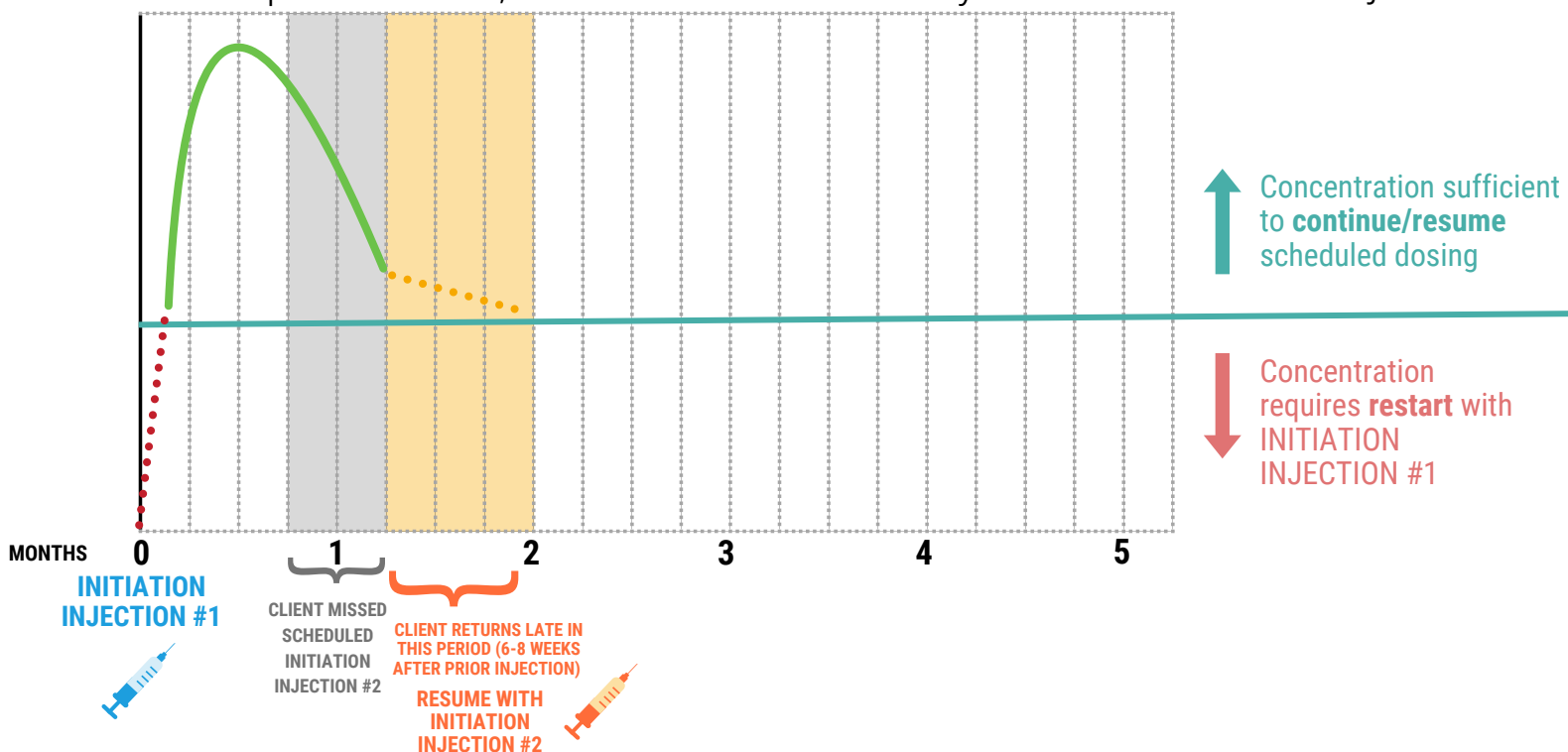


This graph depicts CAB concentration changes between CAB-LA injections in a client who returns as scheduled (no delays).



## CAB-LA SCENARIO 2 (MISSED INIT INJ #2): UNSCHEDULED LATE RETURN FOR CAB-LA INITIATION INJECTION #2 IN 6-8 WEEK PERIOD SINCE PRIOR INJECTION

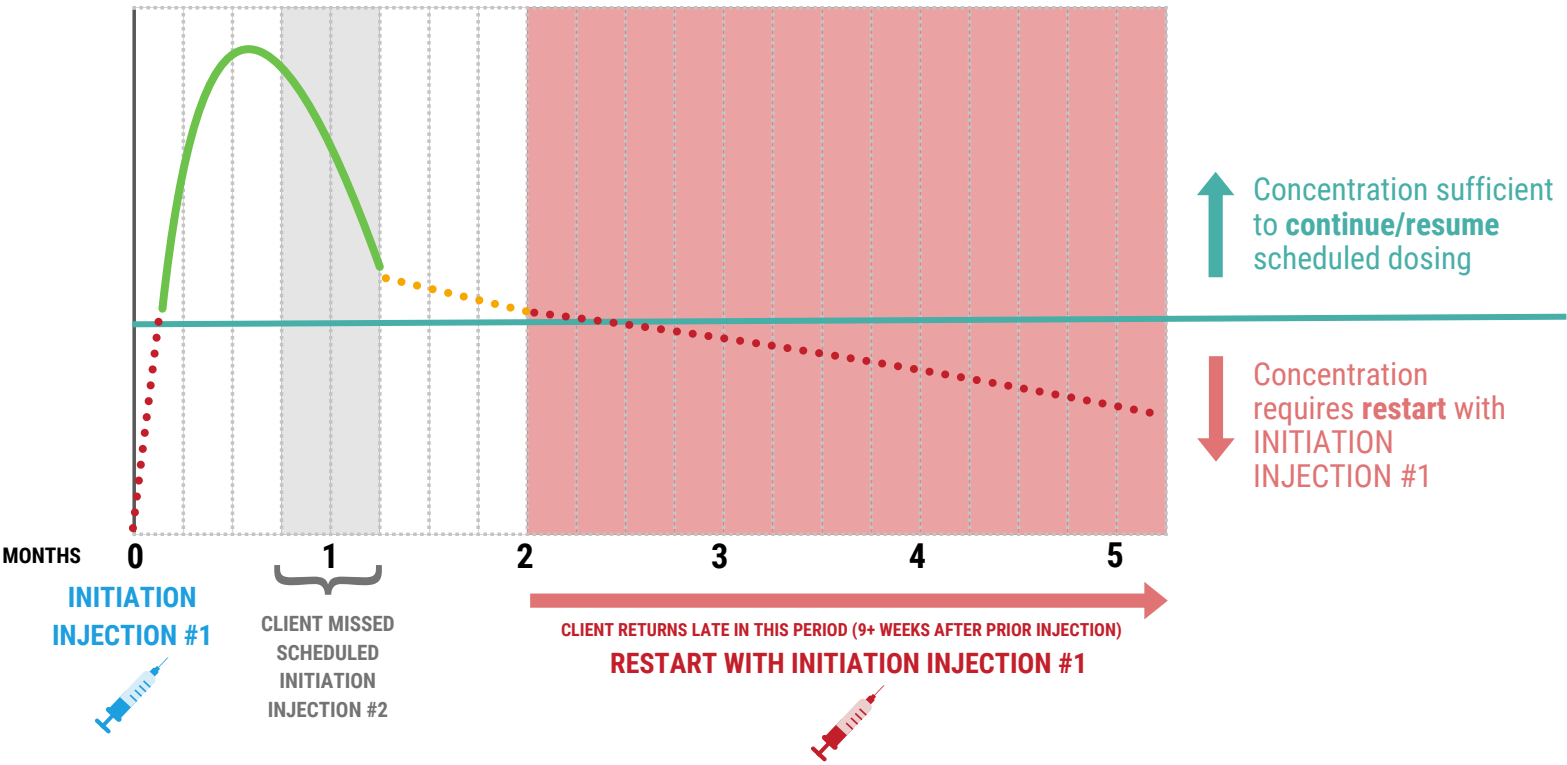
Client missed their scheduled INITIATION INJECTION #2 but returns 6-8 weeks after prior injection. Protection in this period uncertain, but CAB-LA restart not necessary. Resume with INITIATION INJECTION #2.





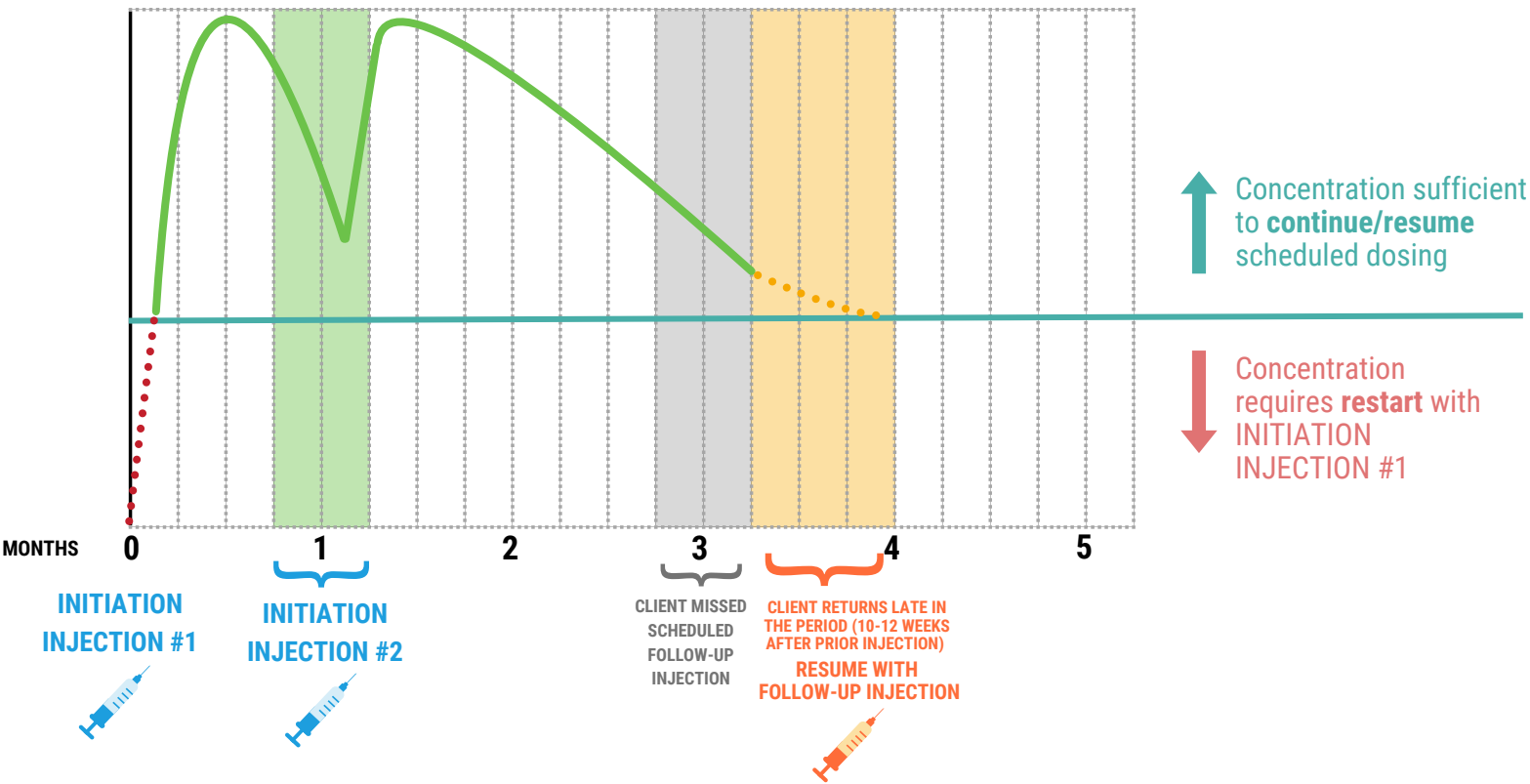
**CAB-LA SCENARIO 3 (MISSED INIT INJ #2): UNSCHEDULED LATE RETURN FOR CAB-LA INITIATION INJECTION #2 IN WEEKS 9+ SINCE PRIOR INJECTION**

Client missed their scheduled INITIATION INJECTION #2 but returns 9+ weeks after prior injection. No protection in this period. Restart CAB-LA with INITIATION INJECTION #1.



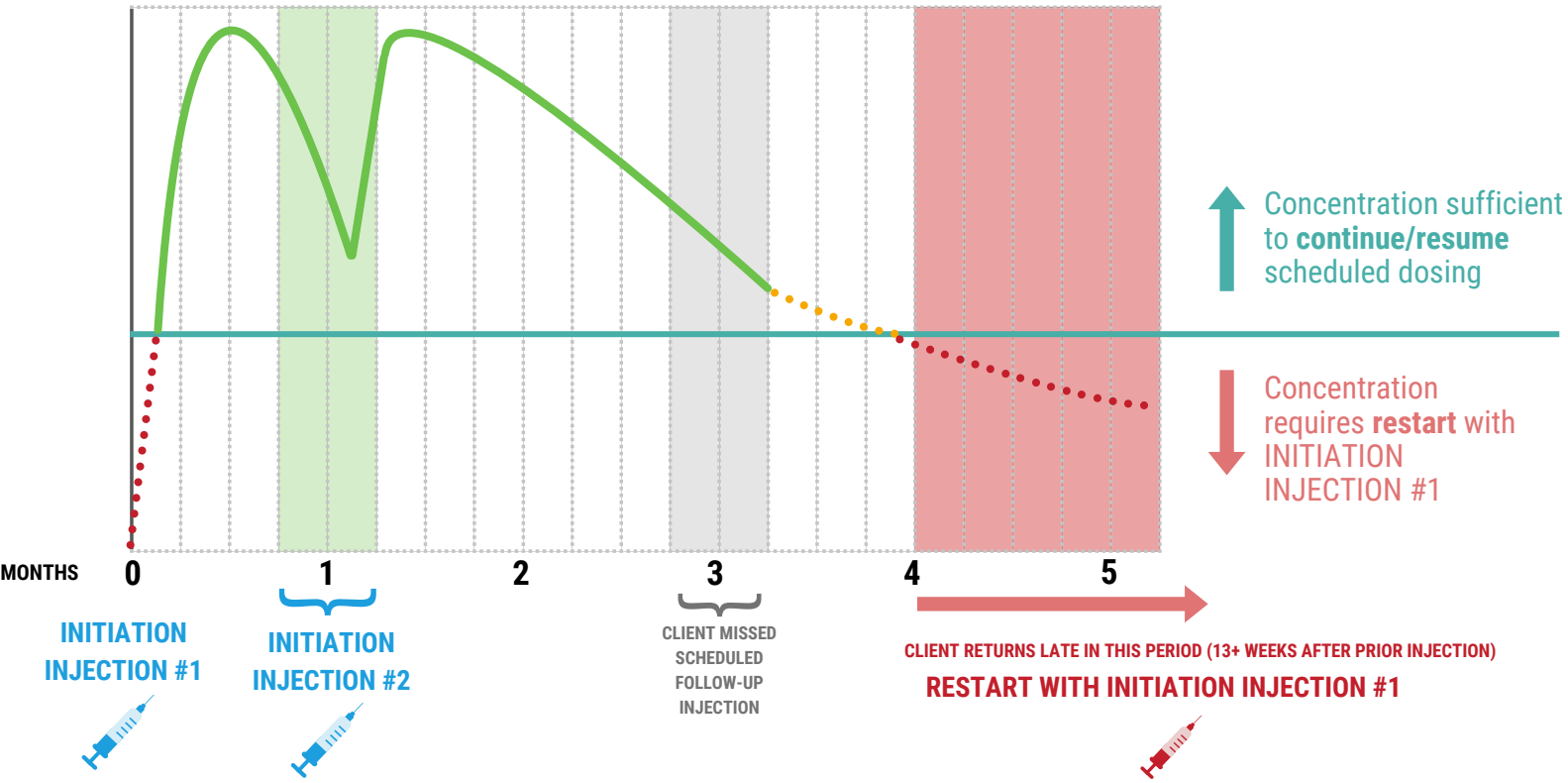
**CAB-LA SCENARIO 4 (MISSED FOLLOW-UP INJ): UNSCHEDULED LATE RETURN FOR CAB-LA FOLLOW-UP INJECTION IN 10-12 WEEK PERIOD SINCE PRIOR INJECTION**

Client missed their scheduled FOLLOW-UP INJECTION but returns 10-12 weeks after prior injection. Protection in this period uncertain, but CAB-LA restart not necessary. Resume with FOLLOW-UP INJECTION.



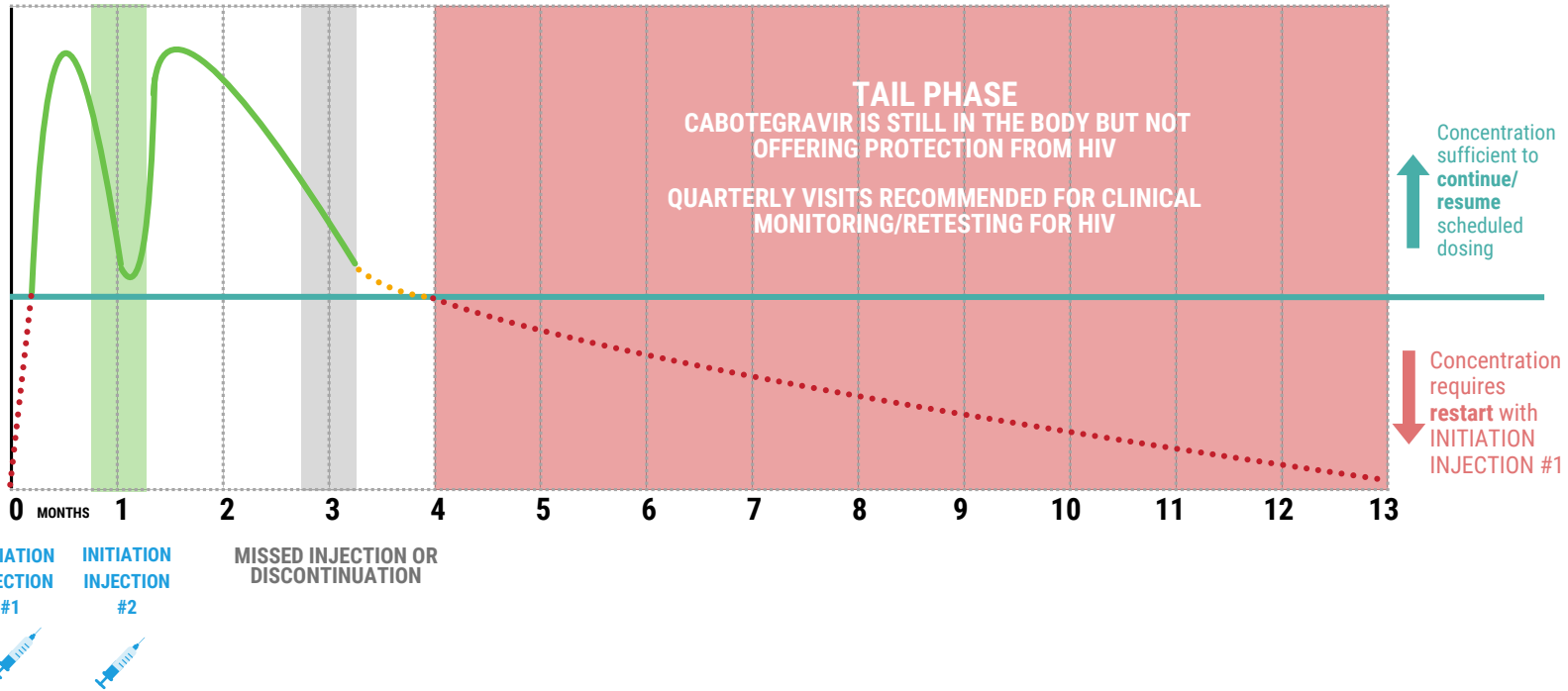
CAB-LA SCENARIO 5 (MISSED FOLLOW-UP INJ): UNSCHEDULED LATE RETURN FOR CAB-LA FOLLOW-UP INJECTION IN WEEKS 13+ SINCE PRIOR INJECTION

Client missed their scheduled FOLLOW-UP INJECTION but returns 13+ weeks after prior injection. No protection in this period. Restart CAB-LA with INITIATION INJECTION #1.



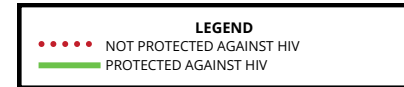
CAB-LA SCENARIO 6 (DISCONTINUATION): THE TAIL PHASE

Because injectable cabotegravir is long-acting, the drug remains in the body for 12 months after the last injection; however, drug levels decrease over time and do not offer protection against HIV.

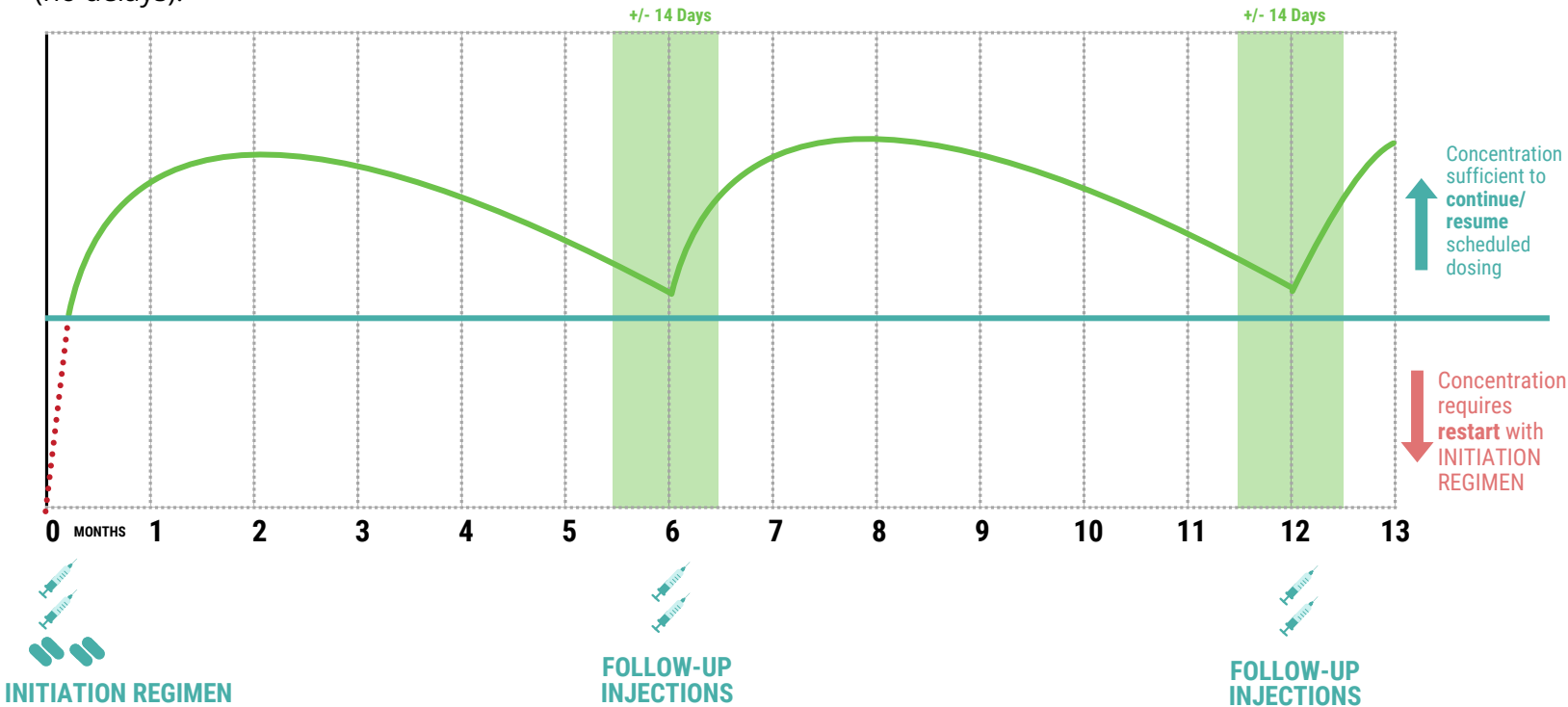


# JOB AID: LEN CONCENTRATION CHANGE SCENARIOS

## LENACAPAVIR SCENARIO 1: LEN INITIATION AND ON-TIME RETURN FOR ALL REINJECTIONS

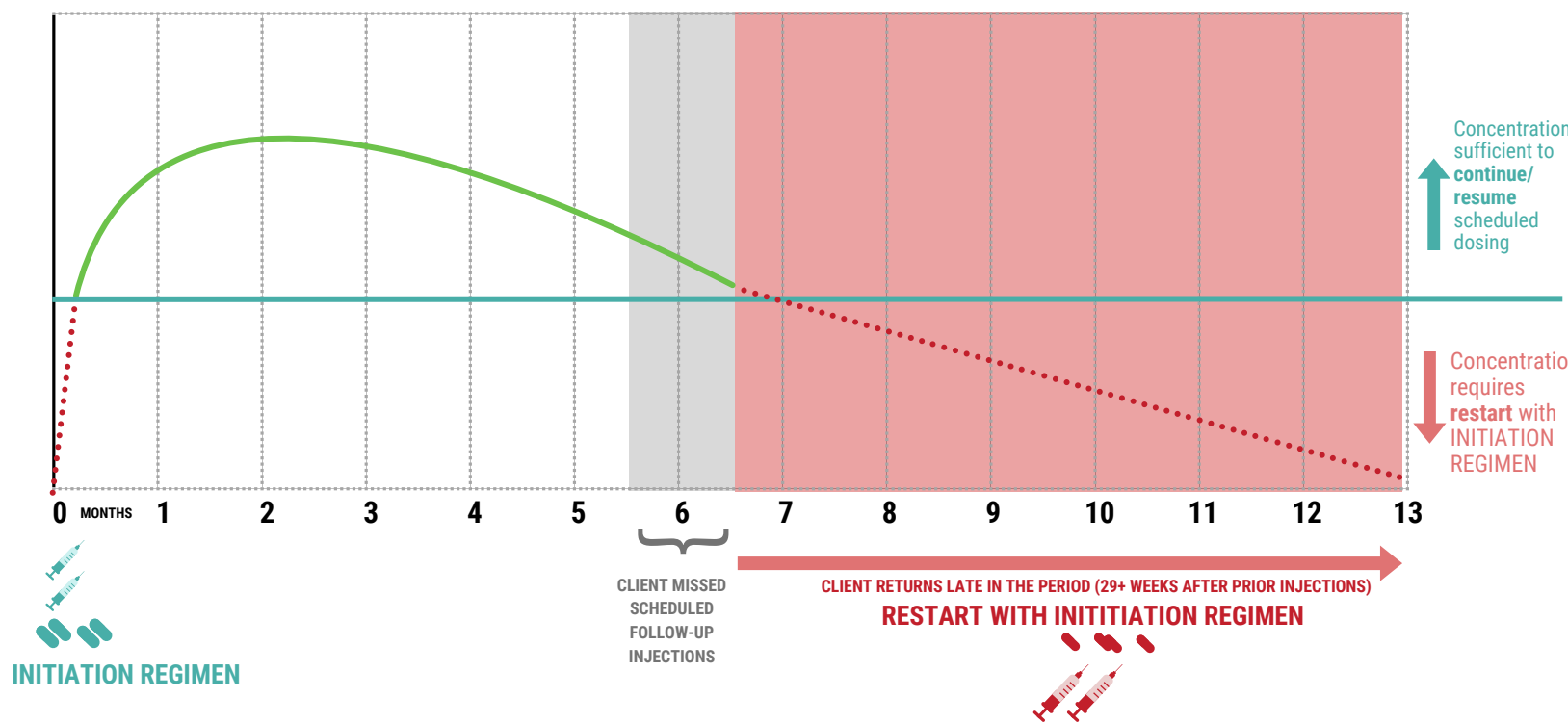


This graph depicts LEN concentration changes between LEN injections in a client who returns as scheduled (no delays).



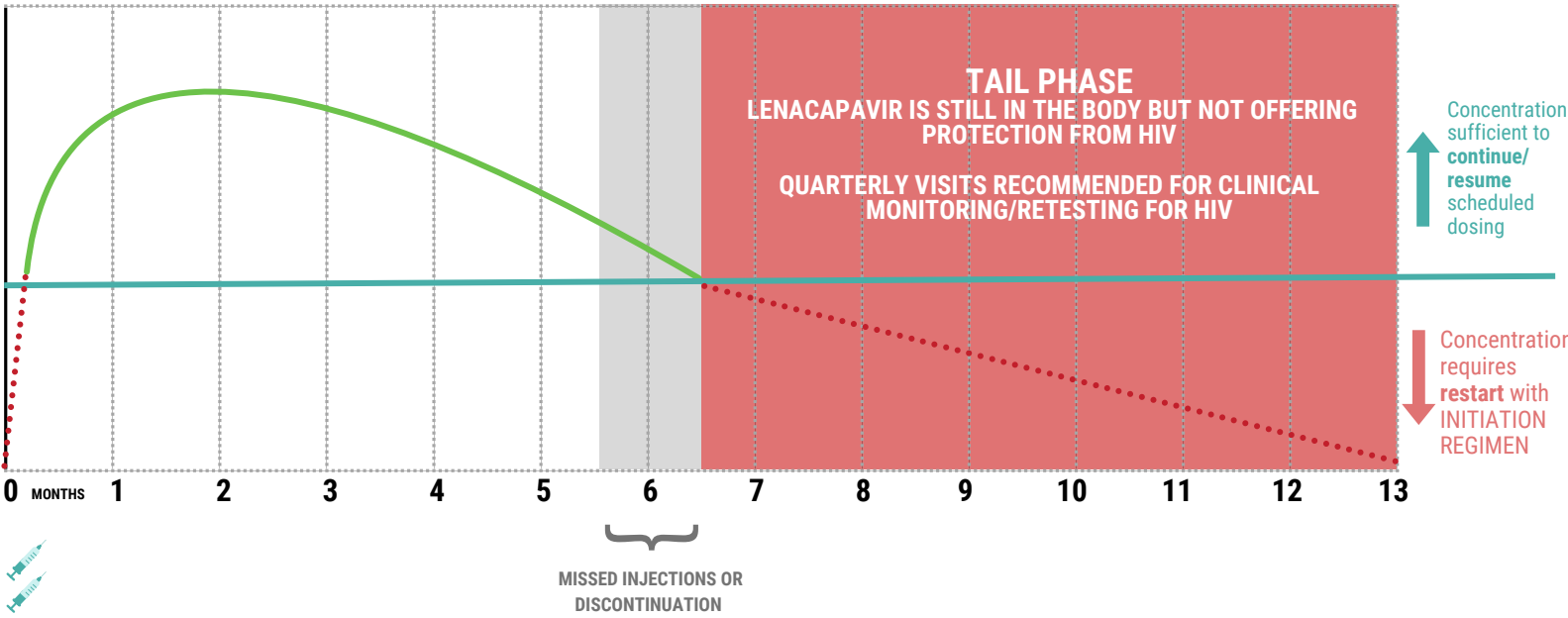
## LENACAPAVIR SCENARIO 2 (MISSED FOLLOW-UP INJECTION): UNSCHEDULED LATE RETURN FOR LEN FOLLOW-UP INJECTIONS >28 WEEKS SINCE PRIOR INJECTION

Client missed their scheduled FOLLOW-UP INJECTION but returns 29+ weeks after prior injection. No protection in this period. Restart LEN with INITIATION REGIMEN.



LENACAPAVIR SCENARIO 3 (DISCONTINUATION): THE TAIL PHASE

Because injectable lenacapavir is long-acting, the drug remains in the body for 12 months after the last injection; however, drug levels decrease over time and do not offer protection against HIV.



# JOB AID: PREP PRODUCT USE CONSIDERATIONS FOR STARTING, CONTINUING, STOPPING, AND USE IRREGULARITIES

## STARTING REGIMEN AND TIME TO PROTECTION

This same information applies to clients restarting the product after discontinuation or specified period of non-use

ORAL PrEP 		DAPIVIRINE VAGINAL RING 	LONG-ACTING CABOTEGRAVIR 	LENACAPAVIR 
<b>Group A</b>  Client takes 1 pill per day taken for 7 consecutive days	<b>Group B</b>  Client takes 2 pills taken together ("loading dose")	Client or provider Inserts DVR according to insertion instructions	Administer two CAB-LA injections 1 month apart (+/- 7 days) according to injection instructions  Day 0 <ul style="list-style-type: none"><li>• Provider administers INITIATION INJECTION 1</li></ul> Month 1 <ul style="list-style-type: none"><li>• Provider administers INITIATION INJECTION 2</li></ul>	Administer multiple doses of oral and injectable LEN, referred to as LEN INITIATION REGIMEN, over two consecutive days:  Day 0 <ul style="list-style-type: none"><li>• Provider administers INITIATION INJECTION 1 &amp; INITIATION INJECTION 2 in separate locations, according to injection instructions</li><li>• Client takes 2 LEN pills, referred to as LOADING PILLS 1 &amp; 2</li></ul> Day 1 <ul style="list-style-type: none"><li>• Client takes 2 LEN pills, referred to as LOADING PILLS 3 &amp; 4</li></ul>
  Protection begins after 7 consecutive days of use	  Protection begins 2-24 hours after loading dose; loading dose ideally taken closer to 24 hours before sex*		  Protection begins approximately 1 week after INITIATION INJECTION 1	  Protection begins within 1 day of completing INITIATION INJECTIONS 1 & 2 and LOADING PILLS 1 & 2 (Day 0) in the INITIATION REGIMEN

**Group A:** Cis women, trans women taking gender-affirming hormones, trans men, and anyone using TDF-based oral PrEP to prevent HIV from injecting practices  
**Group B:** Cisgender men and transgender women not taking gender-affirming hormones using TDF-based oral PrEP to prevent sexual acquisition of HIV  
\*applies whether client using TDF-based oral PrEP continuously or as event-driven regimen

## CONTINUING USE AND SUSTAINING PROTECTION AFTER PROTECTION ONSET

### ORAL PrEP



#### Group A

Client takes 1 pill/day for as long as protection is needed, which may be an indefinite period for some, and shorter-term for others

#### Group B

Client takes 1 pill/day for as long as protection is needed, which may be an indefinite period for some, and shorter-term for others\*

### DAPIVIRINE VAGINAL RING



Client leaves DVR in place, regardless of timing/frequency of sex (or menstruation) and should not remove it immediately after sex, since protection against HIV rapidly declines after removal. The DVR should only be removed after it has been in place for one month

### LONG-ACTING CABOTEGRAVIR



**BIMONTHLY:** Provider administers **FOLLOW-UP INJECTIONS** every **TWO** months (+/- 7 days) according to injection instructions

### LENACAPAVIR



**BIANNUAL:** Provider administers **FOLLOW-UP INJECTIONS** every **SIX** months/26 weeks (+/- 14 days) according to injection instructions

## MISSED DOSES

For all products, clients missing multiple doses or experiencing longer durations of non-use may need to be re-tested for HIV and clinically assessed for PEP indication and AHI suspicion before restarting or continuing PrEP

Client should take missed dose as soon as able, but should not take more than 2 doses on one day

Client should take missed dose as soon as able, but should not take more than 2 doses on one day

If DVR not inserted, insert it as soon as able

For clients who missed a scheduled injection, provider determines whether to Restart or Resume:

If last injection was INITIATION INJECTION #1:

- ≤ 2 months elapsed, Resume with INITIATION INJECTION #2
- >2 months elapsed, Restart with INITIATION INJECTION #1

If last injection was INITIATION INJECTION #2 or FOLLOW-UP INJECTION:

- ≤3 months elapsed, Resume with FOLLOW-UP INJECTION
- >3 months elapsed, Restart with INITIATION INJECTION #1

For clients who missed a scheduled injection, provider determines whether to Restart or Resume:

- If ≤28 weeks since prior injection, Resume with FOLLOW-UP INJECTION
- If >28 weeks since prior injection Restart LEN with all doses (oral and injectable) in the INITIATION REGIMEN

**Group A:** Cis women, trans women taking gender-affirming hormones, trans men, and anyone using TDF-based oral PrEP to prevent HIV from injecting practices

**Group B:** Cisgender men and transgender women not taking gender-affirming hormones using TDF-based oral PrEP to prevent sexual acquisition of HIV

\*applies whether client using TDF-based oral PrEP continuously or as event-driven regimen



## TO DISCONTINUE USE AND ONGOING CLINICAL MONITORING

### ORAL PrEP



#### Group A

Client continues to take 1 pill/day for 7 additional days after the last day of exposure

Post-discontinuation clinical monitoring not necessary

#### Group B

Client continues to take 1 pill/day for 2 additional days after the last day of exposure\*

Post-discontinuation clinical monitoring not necessary

### DAPIVIRINE VAGINAL RING



Provider or client removes DVR according to removal instructions, and protection ends upon removal

Post-discontinuation clinical monitoring not necessary

### LONG-ACTING CABOTEGRAVIR



CAB-LA remains in the body for approximately 1 year after last injection (the “tail” period), with levels too low to provide protection in final 10-11 months of the tail

Post-discontinuation quarterly visits throughout tail period recommended for HIV testing and assessment of prevention needs

### LENACAPAVIR



LEN remains in the body for approximately 1 year after last injection (the “tail” period), with levels too low to provide protection in final 6 months of the tail

Post-discontinuation quarterly visits throughout tail period recommended for HIV testing and assessment of prevention needs

#### For Oral TDF-based PrEP:

**Group A:** Cis women, trans women taking gender-affirming hormones, trans men, and anyone using TDF-based oral PrEP to prevent HIV from injecting practices

**Group B:** Cisgender men and transgender women not taking gender-affirming hormones using TDF-based oral PrEP to prevent sexual acquisition of HIV

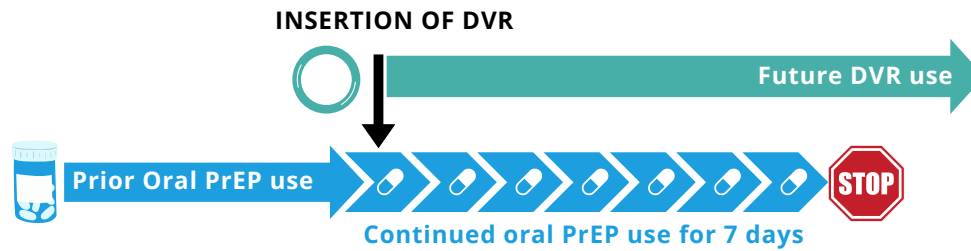
\*applies whether client using TDF-based oral PrEP continuously or as event-driven regimen

# JOB AID: TRANSITIONING BETWEEN PREP PRODUCTS AND OVERLAPPING USE CONSIDERATIONS TO ENSURE PROTECTION

## TRANSITIONING FROM ORAL TDF-BASED PREP

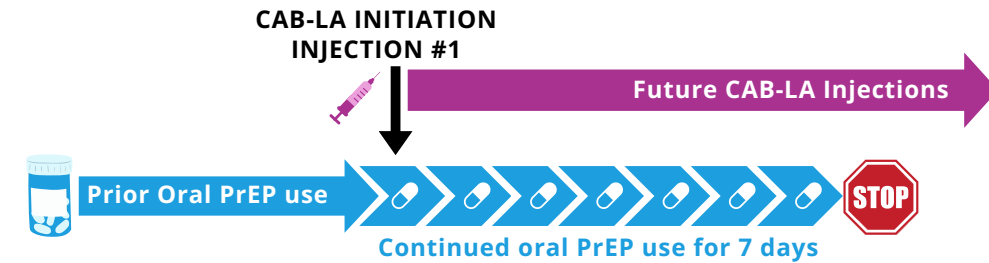
TO DVR

Clients should continue using TDF-based oral PrEP for **7 days** after insertion of DVR



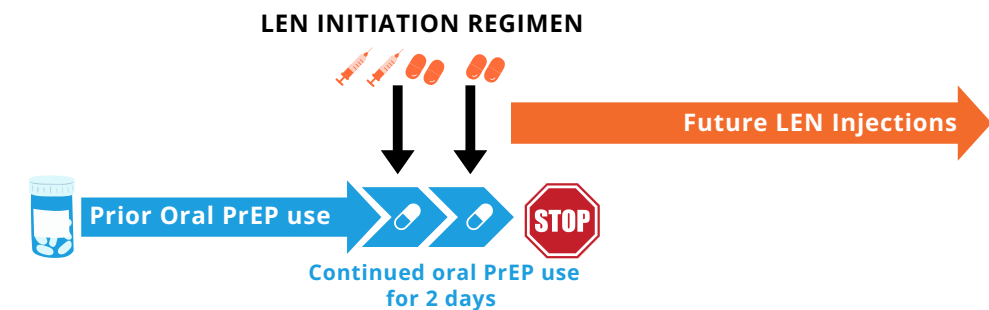
TO CAB-LA

Clients should continue using TDF-based oral PrEP for **7 days** after CAB-LA INITIATION INJECTION #1



TO LEN

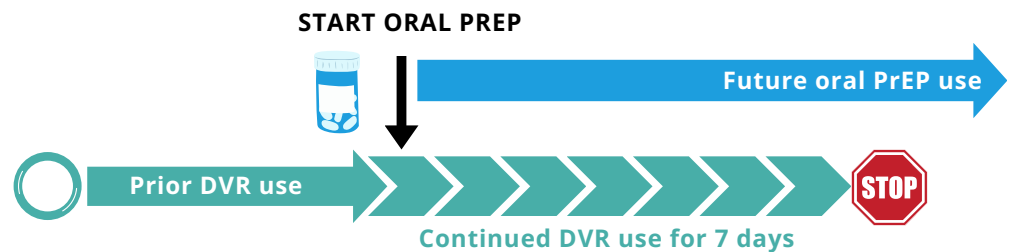
Clients should continue using TDF-based oral PrEP for **2 days** after LEN INITIATION REGIMEN



## TRANSITIONING FROM DAPIVIRINE VAGINAL RING (DVR)

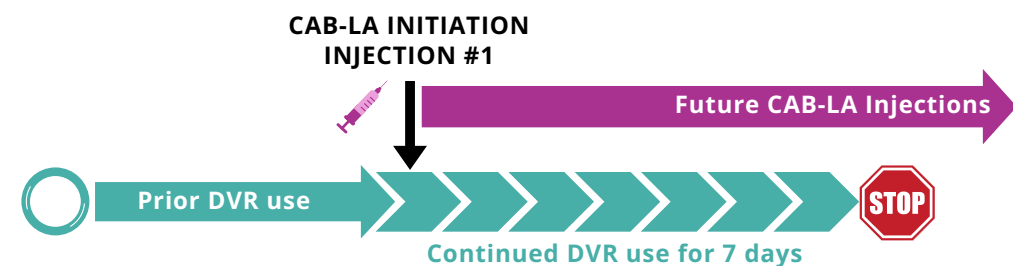
TO ORAL PREP

Clients should continue using DVR for **7 days** after starting TDF-based oral PrEP



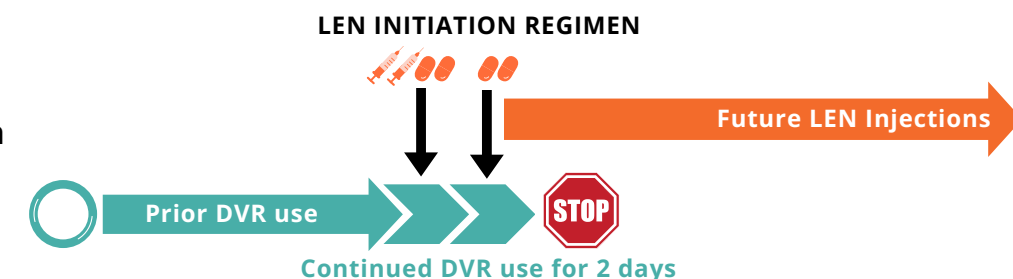
TO CAB-LA

Clients should continue using DVR for **7 days** after CAB-LA INITIATION INJECTION #1



TO LEN

Clients should continue wearing DVR throughout **both days** of receiving the INITIATION REGIMEN to start LEN (all doses)



# TRANSITIONING FROM CAB-LA

TO ORAL PREP

If last injection was INITIATION INJECTION #1, client should begin oral TDF-based PrEP **1 month** after last injection

CAB-LA INITIATION INJECTION #1



START ORAL PREP



Future oral PrEP use

If last injection was INITIATION INJECTION #2 or FOLLOW-UP INJECTION, client should begin oral TDF-based PrEP **2 months** after last injection

Prior CAB-LA use

CAB-LA INITIATION INJECTION #2 or FOLLOW UP INJECTION



START ORAL PREP



Future oral PrEP use

TO DVR

If last injection was INITIATION INJECTION #1, client should insert DVR **1 month** after last injection

CAB-LA INITIATION INJECTION #1



INSERT DVR



Future DVR use

If last injection was INITIATION INJECTION #2 or FOLLOW-UP INJECTION, client should insert DVR **2 months** after last injection

Prior CAB-LA use

CAB-LA INITIATION INJECTION #2 or FOLLOW UP INJECTION



INSERT DVR



Future DVR use

TO LEN

If last CAB-LA injection was INITIATION INJECTION #1, client should start LEN INITIATION REGIMEN **1 month** after last CAB-LA injection

CAB-LA INITIATION INJECTION #1



LEN INITIATION REGIMEN



Future LEN Injections

If last CAB-LA injection was INITIATION INJECTION #2 or FOLLOW-UP INJECTION, client should start LEN INITIATION REGIMEN **2 months** after last CAB-LA injection

Prior CAB-LA use

CAB-LA INITIATION INJECTION #2 or FOLLOW UP INJECTION



LEN INITIATION REGIMEN



Future LEN Injections

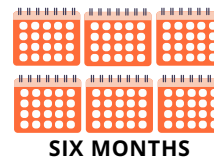
# TRANSITIONING FROM LEN

TO ORAL PREP

Clients should start start TDF-based oral PrEP **6 months** after the last LEN injections were administered, regardless of the type of LEN injections last administered

Prior LEN use

LEN INJECTIONS



START ORAL PREP



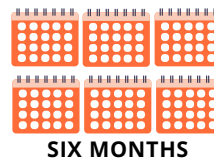
Future oral PrEP use

TO DVR

Clients should insert DVR **6 months** after the last LEN injections were administered, regardless of the type of LEN injections last administered

Prior LEN use

LEN INJECTIONS



INSERT DVR



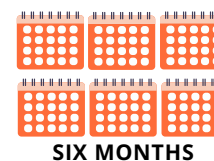
Future DVR use

TO CAB-LA

Clients should start CAB-LA **6 months** after the last LEN injections were administered, regardless of the type of LEN injections last administered

Prior LEN use

LEN INJECTIONS



CAB-LA INIT INJ#1



Future CAB-LA Injections

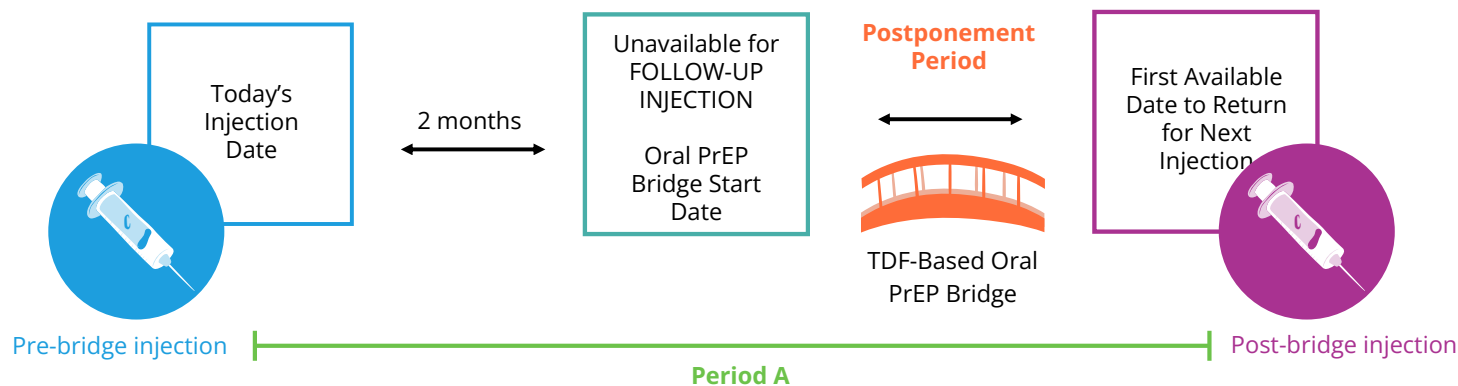
# JOB AID: USING ORAL PREP TO BRIDGE POSTPONED CAB-LA AND LEN INJECTIONS

## CAB-LA

*NOTE: INITIATION INJECTION #2 cannot be postponed*

If a client needs to postpone future CAB-LA FOLLOW-UP INJECTIONS, providers can use TDF-based oral PrEP to 'bridge' between injections. If the provider decides to postpone the next injection with a TDF-based oral PrEP bridge, the client will receive both an injection of CAB-LA and a supply of TDF-based oral PrEP today to take with them, with instructions to start using the TDF-based oral PrEP two months from today and continue using it daily.

- To calculate the number of TDF-based oral PrEP to prescribe, calculate the number of days in the **postponement period** [Period A - 60 days]



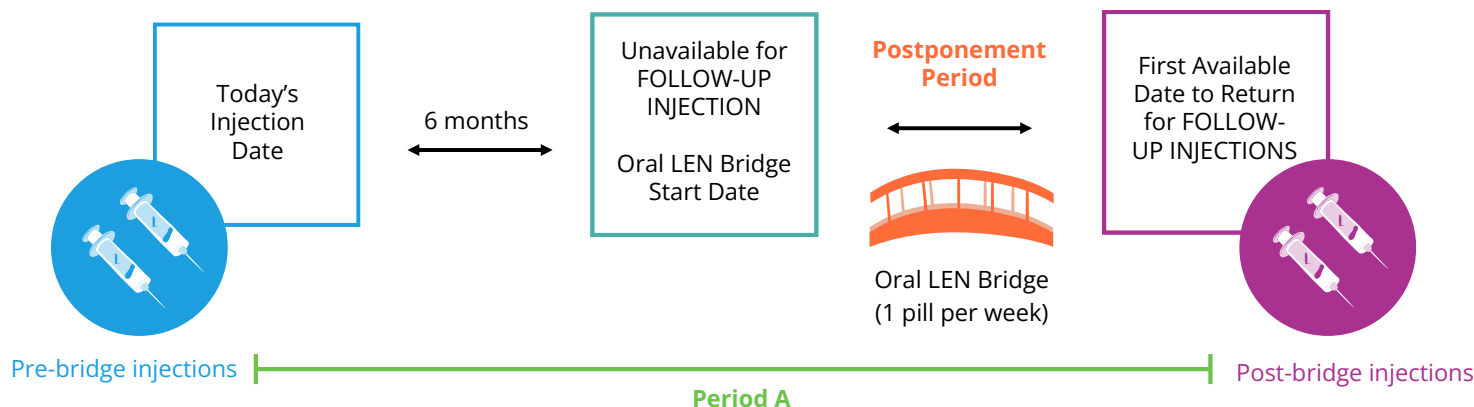
Following the oral PrEP bridge, providers must decide to **resume** or **restart** CAB-LA. This decision is based on duration of time between today's injection date and first available date to return (Period A).

- If period A is  $\leq 3$  months: Resume with FOLLOW-UP INJECTION
- If period A is  $> 3$  months: Restart with INITIATION INJECTION #1 (followed by INITIATION INJECTION #2 one month later)

## LENACAPAVIR

If a client needs to postpone future LEN FOLLOW-UP INJECTIONS, providers can use oral LEN to 'bridge' between injections. If the provider decides to postpone the next injection with oral LEN bridge, the client will receive both LEN injections and a supply of oral LEN today to take with them, with instructions to start using the oral LEN six months from today, taking one pill per week.

- To calculate the number of oral LEN to prescribe, calculate the number of weeks in the postponement period [Period A - 26 weeks]



Following the oral LEN bridge, providers should administer FOLLOW-UP INJECTIONS. It is not necessary to restart LEN with the INITIATION REGIMEN following a bridge with oral LEN, unless adherence to weekly doses was poor.