

# HIV PrEP Medications and Dosing Options

This is a PDF version of the following document:

Module 1: [HIV PrEP Fundamentals](#)

Lesson 3: [HIV PrEP Medications and Dosing Options](#)

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<https://www.hivprep.uw.edu/go/hiv-prep-fundamentals/hiv-prep-medication-options/core-concept/all>.

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## Background

There are four medications approved by the United States Food and Drug Administration (FDA) for HIV preexposure prophylaxis (PrEP): oral tenofovir DF-emtricitabine (TDF-FTC), oral tenofovir alafenamide-emtricitabine (TAF-FTC), long-acting injectable cabotegravir (CAB-LA), and lenacapavir subcutaneous injections (LEN-SQ).<sup>[1,2]</sup> These medications have unique characteristics, and clinicians should be familiar with appropriate indications and populations for use of these medications for HIV PrEP. Tenofovir disoproxil fumarate (TDF), tenofovir alafenamide (TAF), and emtricitabine (FTC) are nucleoside reverse transcriptase inhibitors (NRTIs). The NRTIs work by blocking the HIV enzyme reverse transcriptase, which plays a critical role in converting HIV RNA into HIV DNA. Cabotegravir is an integrase strand transfer inhibitor (INSTI); this medication inhibits the function of the HIV integrase enzyme, which normally functions to integrate newly formed HIV DNA into human DNA. Lenacapavir is a capsid inhibitor that has multiple sites of action in the HIV life cycle, including restriction of nuclear import of the HIV capsid core, inhibition of HIV capsid disassembly, and alterations in capsid assembly.

[Activity] A. Medications: Mechanism of Action

## HIV PrEP Medications

### Tenofovir DF-emtricitabine (TDF-FTC)

- **Indication:** Tenofovir DF-emtricitabine (TDF-FTC) is indicated by the FDA for HIV PrEP to reduce the risk of sexually acquired HIV in adults and adolescents (weighing at least 35 kg) who are at risk of acquiring HIV. Individuals must have a negative HIV test prior to starting TDF-FTC for HIV PrEP. Although TDF-FTC does not have an FDA indication to prevent HIV through injection drug use, it is recommended by the Centers for Disease Control and Prevention (CDC) as HIV PrEP for people who inject drugs (PWID).
- **Formulation:** A single oral tablet of TDF-FTC is a two-drug fixed-dose combination that consists of tenofovir DF (TDF) 300 mg and emtricitabine (FTC) 200 mg. In the United States, there are now multiple generic versions of TDF-FTC, and these generic versions are at a dramatically reduced price compared with the brand-name medication.[[3,4](#)]
- **Dosing:** Tenofovir DF-emtricitabine is a two-drug, fixed-dose combination that contains 300 mg of tenofovir DF and 200 mg of emtricitabine. For HIV PrEP, TDF-FTC is approved for 1 tablet daily dosing. It is also used off-label as on-demand (2:1:1) non-daily dosing for men who have sex with men.
- **Food Requirements:** Take with or without food.
- **Use in Persons with Renal Impairment:** For use as HIV PrEP, TDF-FTC is not recommended in persons who have an estimated creatinine clearance less than 60 mL/min.
- **Use in Persons with Hepatic Impairment:** The pharmacokinetics of tenofovir DF (TDF) have been studied in persons with moderate to severe hepatic impairment and no substantial alterations in tenofovir pharmacokinetics were observed. The pharmacokinetics of TDF-FTC have not been studied in persons with hepatic impairment, but FTC is not significantly metabolized by liver enzymes, so the impact of liver impairment on FTC is likely to be limited. Dosage adjustment of TDF-FTC is not recommended in individuals with hepatic impairment.[[5](#)]
- **Side Effects:** Tenofovir DF (TDF) has been associated with nephrotoxicity and decreased bone mineral density when used for HIV treatment, but renal adverse events in large HIV PrEP trials were similar to or only slightly more common with TDF-FTC versus placebo.[[6,7,8](#)] In addition, small decreases in bone mineral density among persons taking TDF-based HIV PrEP have been shown to reverse after HIV PrEP discontinuation.[[9,10,11](#)] Serum lipid profiles are not adversely impacted by TDF-FTC.

### Tenofovir alafenamide-emtricitabine (TAF-FTC)

- **Indication:** Tenofovir alafenamide-emtricitabine (TAF-FTC) is indicated for HIV PrEP in adults and adolescents (weighing at least 35 kg) who are at risk of sexually acquiring HIV, excluding individuals at risk of acquiring HIV from receptive vaginal sex. Individuals must have a negative HIV test prior to starting TAF-FTC for HIV PrEP. Although TAF-FTC is not FDA-approved to prevent acquisition of HIV through receptive vaginal sex, there are unpublished data that suggest an 89% reduction in risk for HIV acquisition in women who had biomarker evidence of taking at least a mean of 2 doses of TAF-FTC per week.[[12](#)]
- **Formulation:** A single oral tablet of TAF-FTC is a two-drug fixed-dose combination that contains 25 mg of tenofovir alafenamide (TAF) and 200 mg of emtricitabine (FTC).
- **Dosing:** For HIV PrEP dosing, TAF-FTC should be taken as one tablet once daily. Alternative dosing, such as on-demand use, has not been adequately studied and is not recommended.
- **Food Requirements:** Take with or without food.
- **Use in Persons with Renal Impairment:** For HIV PrEP, use of TAF-FTC is not recommended for persons who have an estimated creatinine clearance of less than 30 mL/min, unless they are receiving chronic hemodialysis. For those on hemodialysis, TAF-FTC should be taken as a once daily dose, but should be given after hemodialysis on the days of hemodialysis.
- **Use in Persons with Hepatic Impairment:** Dosage adjustment of TAF-FTC is not recommended in individuals with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. Use of

TAF-FTC in individuals with severe hepatic impairment (Child-Pugh Class C) has not been adequately studied.

- **Side Effects:** Daily TAF-FTC has been shown to have more favorable effects on bone mineral density and renal biomarkers when compared to daily TDF-FTC, but TAF-FTC has been associated with greater weight gain and less favorable lipid profiles.[1,13] When used as daily HIV PrEP, TAF-FTC caused a slight decrease in high-density lipoprotein (HDL) levels, a slight increase in triglyceride levels, but no change in total cholesterol or low-density lipoprotein (LDL) levels.[13]

## Long-Acting Injectable Cabotegravir injections (CAB-LA)

- **Indication:** Long-acting injectable cabotegravir (CAB-LA) is indicated for HIV PrEP in adults and adolescents (weighing at least 35 kg) to prevent sexual acquisition of HIV.
- **Formulation:** CAB-LA is available in a 200 mg/mL solution and is administered as a 3 mL intramuscular injection in the gluteal region. Oral cabotegravir is a 30 mg tablet that is taken once daily.
- **Dosing:** CAB-LA is given as a single 600 mg (3 mL) injection 1 month apart for 2 consecutive months and then every 2 months thereafter. An optional lead-in with oral cabotegravir 30 mg once daily may be used for approximately 1 month to assess the tolerability of cabotegravir. If the oral cabotegravir lead-in is used, the first injection of CAB-LA should be given on the last day of the oral lead-in (or within 3 days of completing the oral lead-in).
- **Food Requirements:** Oral cabotegravir can be taken with or without food. There are no food restrictions with CAB-LA.
- **Use in Persons with Renal Impairment:** For HIV PrEP, cabotegravir has no renal restrictions. For persons who have a creatinine clearance less than 30 mL/min, increased monitoring for cabotegravir toxicity is recommended. Hemodialysis is not expected to impact cabotegravir levels.
- **Use in Persons with Hepatic Impairment:** Dosage adjustment of CAB-LA is not recommended in individuals with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. Use of CAB-LA in individuals with severe hepatic impairment (Child-Pugh Class C) has not been adequately studied.
- **Side Effects:** Injection site reactions are the most common adverse events with CAB-LA, with pain and tenderness being the most common symptoms.[14,15]

## Lenacapavir Subcutaneous Injections (LEN-SQ)

- **Indication:** Lenacapavir subcutaneous injection (LEN-SQ) is indicated for HIV PrEP in adults and adolescents (weighing at least 35 kg) to prevent sexual acquisition of HIV. There are two lenacapavir medications available for commercial use—lenacapavir-SQ (*Yeztugo*) for HIV PrEP and lenacapavir SQ (*Sunlenca*) as a component of HIV antiretroviral treatment. Although these two lenacapavir subcutaneous injection medications contain the same recommended dose and timing for administration, it is important to designate and choose the correct brand, based on whether the indication for use is HIV PrEP or HIV treatment. In addition, there are two different oral brand preparations: oral lenacapavir (*Yeztugo*) for HIV PrEP and oral lenacapavir (*Sunlenca*) as a component of HIV treatment.
- **Formulation:** Lenacapavir subcutaneous injection (LEN-SQ) is available in 1.5 mL vials that contain 463.5 mg of lenacapavir. Lenacapavir is also available as a 300 mg tablet (LEN-PO) that can be taken with or without food.
- **Dosing:** Use of LEN-SQ for HIV PrEP requires a 2-day initiation phase that uses both oral and injection doses. Day 1 of the initiation phase requires a 600 mg (2 x 300 mg tablets) dose of oral lenacapavir and a 927 mg dose (2 x 463.5 mg injections) of LEN-SQ. Day 2 of the initiation phase requires a 600 mg (2 x 300 mg tablets) dose of oral lenacapavir. After the 2-day initiation phase, the LEN-SQ 927 mg dose (2 x 463.5 mg injections) is administered every 26 weeks (approximately every 6 months).
- **Food Requirements:** Oral lenacapavir can be taken with or without food. There are no food restrictions with LEN-SQ.

- **Use in Persons with Renal Impairment:** There are no dosage adjustments of LEN-SQ or oral lenacapavir in persons with mild, moderate, or severe renal insufficiency. There are insufficient data on the use of LEN-SQ or oral lenacapavir in persons who have a creatinine clearance less than 15 mL/min. In addition, there are insufficient data on the use of LEN-SQ or oral lenacapavir in persons receiving hemodialysis, but lenacapavir is highly protein bound and thus hemodialysis is not likely to significantly impact lenacapavir levels.
- **Use in Persons with Hepatic Impairment:** Dosage adjustment of LEN-SQ is not recommended in individuals with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. Use of LEN-SQ in individuals with severe hepatic impairment (Child-Pugh Class C) has not been studied.
- **Side Effects:** The most common adverse reactions with LEN-SQ are injection site reactions, nausea, and headache. Injection site reactions include immediate-onset acute inflammatory reactions (onset hours to 1–2 days) and delayed or prolonged reactions that typically manifest as subcutaneous nodules (onset after 1–2 days and may persist for months).

## Cabotegravir Guide

Review the Information Guide on *Long-Acting Injectable Cabotegravir for HIV PrEP* ([Figure 1](#)) and answer the Check on Learning questions below.

[Q] Cabotegravir Dosing

[Q] Acceptable Time Ranges with Cabotegravir Dosing

## Lenacapavir Guide

Review the Information Guide on *Lenacapavir for HIV PrEP* ([Figure 2](#)) and answer the Check on Learning questions below.

[Q] Lenacapavir Subcutaneous Injection Technique

[Q] Lenacapavir Oral Bridge

## Use of HIV PrEP Medications with Renal Insufficiency

Among the four medications recommended for HIV PrEP, only TDF-FTC is associated with a significant risk of nephrotoxicity. The following table summarizes recommendations for the use of HIV PrEP medications in persons with renal insufficiency ([Table 1](#)). These recommendations are based on the prescribing information for TDF-FTC, TAF-FTC, CAB-LA, and LEN-SQ.

[Q] Use of TDF-FTC with Renal Insufficiency

## On-Demand (2-1-1) Oral HIV PrEP

On-demand HIV PrEP is the concept of taking oral HIV PrEP centered around specific sexual events.[1,16] The term on-demand HIV PrEP is also commonly referred to as 2-1-1 or non-daily PrEP. Since CAB-LA is not administered on a daily basis and is not taken on an on-demand basis, we recommend not using the older term “non-daily” HIV PrEP when describing on-demand or 2-1-1 HIV PrEP. On-demand HIV PrEP with TDF-FTC was shown to be highly effective for MSM in the French IPERGAY study.[16] Oral TDF-FTC is the only medication that has been studied for use as on-demand HIV PrEP.

- **Recommendations for On-Demand HIV PrEP:** On-demand HIV PrEP is only recommended with oral TDF-FTC and only when used in MSM. Although TDF-FTC is not FDA-approved specifically for use as on-demand HIV PrEP, several major guidelines recommend on-demand TDF-FTC as an HIV PrEP option for MSM.[1,17] There are no other medications that are FDA-approved or recommended for use as on-demand HIV PrEP.
- **Dosing Schedule with On-Demand HIV PrEP:** The recommended TDF-FTC dosing schedule for on-demand HIV PrEP (for a single episode of sex) consists of taking two tablets 2-24 hours before sex, one tablet 24 hours after the initial 2-pill dosing, and one tablet 48 hours after the initial 2-pill dosing. If sexual activity continues, one tablet daily of TDF-FTC should continue, ensuring that two doses (taken 24 hours apart) have been taken after the last sexual encounter.

### Exercise

- Review the *On-Demand HIV PrEP Guide* below ([Figure 3](#)) and use this guide to answer the Check on Learning questions below.

[Q] On-Demand Dosing

[Q] On-Demand Dosing for Multiple Sex Episodes

[Q] On Demand Dosing after Gap of 24 hours Since Last Dose

## Choice of PrEP Medication for Selected Groups

Choosing an appropriate HIV PrEP medication should take into account multiple factors, including type of sexual activity the patient engages in, FDA approval for the indication you are considering prescribing, patient preference for oral versus injectable, renal function, hepatitis B status, medication cost, financial and insurance considerations, and clinic infrastructure for providing the HIV PrEP medications. The table below summarizes major indications for each of the three FDA-approved HIV PrEP medications and how the CDC recommends using these medications for HIV PrEP ([Table 2](#)).

### Exercise for Choosing HIV PrEP Medications

Review the section and table above related to *Choice of HIV PrEP Medications for Selected Groups* and then answer each of the 8 case scenarios in this interactive exercise. ([Figure 5](#)) *NOTE:* this exercise is in the process of being updated to incorporate the option of using lenacapavir subcutaneous injection (LEN-SQ) for HIV PrEP.

## HIV PrEP Tools for Clinicians: Medications

The *National HIV PrEP Curriculum* team has created **HIV PrEP Tools for Clinicians** based on the 2021 CDC HIV PrEP Guidelines.<sup>[1]</sup> These tools includes a component on **Medications for HIV PrEP** that provides a step-by-step determination to guide the appropriate choice of HIV PrEP medications. These tools also provides a guide for the assessment for HIV PrEP indications and a guide to baseline and monitoring laboratory evaluation. It is important to note that these tools are intended to help guide and educate clinicians, but all final decisions regarding indications for HIV PrEP, medication choices, and laboratory monitoring should be based on the clinician's judgment ([Figure 6](#)). Access these tools by clicking [TOOLS](#) on the top navigation bar; once on the Tools page you can use any of the tools directly on the website and by installing it on your mobile device. *NOTE: The HIV PrEP Tools for Clinicians is in the process of revision to include lenacapavir as an option for HIV PrEP.*



## Summary Points

- The FDA has approved four medications for HIV PrEP usage: oral TDF-FTC, oral TAF-FTC, CAB-LA, and LEN-SQ. A negative HIV test is recommended prior to initiation of HIV PrEP, regardless of which medication is used.
- Oral TDF-FTC is indicated for HIV PrEP in adults and adolescents who weigh at least 35 kg (77 lb) to prevent sexual acquisition of HIV infection. For persons with an estimated creatinine clearance less than 60 mL/min, TDF-FTC is not recommended. Oral TDF-FTC is also recommended by the CDC to prevent HIV acquisition for people who inject drugs.
- Oral TAF-FTC is indicated for HIV PrEP in adults and adolescents who weigh at least 35 kg (77 lb) to prevent sexual acquisition of HIV, excluding individuals at risk of acquiring HIV from receptive vaginal sex. For persons with an estimated creatinine clearance less than 30 mL/min, TAF-FTC is not recommended, unless the person is receiving chronic hemodialysis.
- CAB-LA is indicated for HIV PrEP in adults and adolescents who weigh at least 35 kg (77 lb) to prevent sexual acquisition of HIV. CAB-LA is administered as a single 600 mg (3 mL) injection 1 month apart for 2 consecutive months and then every 2 months thereafter. An optional lead-in with oral cabotegravir 30 mg once daily may be used for approximately 1 month to assess the tolerability of cabotegravir. There are no renal restrictions, except that cabotegravir has not been studied in persons with end-stage renal disease (CrCl less than 15 mL/min) who are not on hemodialysis.
- LEN-SQ is indicated for HIV PrEP in adults and adolescents who weigh at least 35 kg (77 lb) to prevent sexual acquisition of HIV. Use of lenacapavir for HIV PrEP requires a 2-day initiation phase dosing followed by LEN-SQ administered as a 927 mg dose of lenacapavir (two 463.5 mg injections) every 6 months. There are no renal restrictions, except that lenacapavir has not been studied in persons with end-stage renal disease (CrCl less than 15 mL/min) who are not on hemodialysis.
- On-demand (2-1-1) HIV PrEP is only recommended with oral TDF-FTC and only when used for MSM. Dosing for a single episode of sex is two tablets 2 to 24 hours before sex, one tablet 24 hours after the first two tablets, and one tablet 48 hours after the initial two tablets. With ongoing sexual activity, TDF-FTC one tablet daily (at 24-hour intervals) should continue until two doses have been given (24 hours apart) after the last sexual encounter.
- Factors to consider when choosing an appropriate HIV PrEP medication include the individual's type of sexual activity, medication preferences, renal function, hepatitis B status, medication cost, financial and insurance considerations, and clinic infrastructure for providing injectable medications.
- For MSM there are four recommended options for HIV PrEP: TDF-FTC, TAF-FTC, CAB-LA, and LEN-SQ.
- For women there are three recommended HIV PrEP options for preventing HIV acquisition via vaginal sex: TDF-FTC, CAB-LA, and LEN-SQ. For women who are pregnant, CAB-LA is not recommended due to insufficient safety data.
- For people who inject drugs, TDF-FTC and LEN-SQ are the recommended medications to use for HIV PrEP.
- The use of HIV PrEP medications in adolescents requires the adolescent to weigh at least 35 kg (77 lb).

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# Figures


**Figure 1 Long-Acting Injectable Cabotegravir for HIV PrEP: Guide**



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CLINICIAN'S INFORMATION GUIDE



## Long-Acting Injectable Cabotegravir for HIV PrEP

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### ABOUT THIS INFORMATION GUIDE

This information guide from the *National HIV PrEP Curriculum* is intended for health care professionals involved in the care of persons interested in or receiving HIV preexposure prophylaxis (PrEP). The information in this guide emphasizes the dosing of long-acting injectable cabotegravir (CAB-LA) for HIV PrEP. This guide is produced by the University of Washington Infectious Diseases Education and Assessment Program (IDEA) as part of the federally-funded *National HIV PrEP Curriculum* project.

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### LAST UPDATED


This educational guide was last updated *February 12, 2025*.

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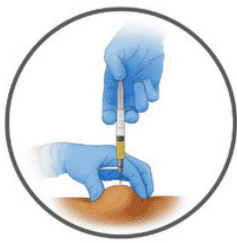
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THIS PROJECT WAS FUNDED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND THE HEALTH RESOURCES AND SERVICES ADMINISTRATION.

**Figure 2 Lenacapavir for HIV PrEP: Guide**


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# Lenacapavir for HIV PrEP

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This information guide from the *National HIV PrEP Curriculum* is intended for health care professionals involved in the care of persons interested in or receiving HIV preexposure prophylaxis (PrEP). The information in this guide emphasizes the dosing and administration of long-acting injectable lenacapavir (LEN) for HIV PrEP. This guide is produced by the University of Washington Infectious Diseases Education and Assessment Program (IDEA) as part of the federally-funded *National HIV PrEP Curriculum* project.

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## LAST UPDATED


This educational guide was last updated *October 6, 2025*.

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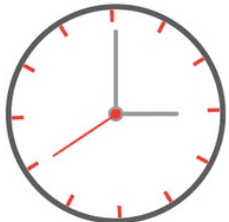


**Figure 3 On-Demand (2-1-1) Dosing for HIV PrEP: Guide**



National **HIV PrEP** Curriculum

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CLINICIAN'S INFORMATION GUIDE

## On-Demand (2-1-1) Dosing for HIV PrEP

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### ABOUT THIS INFORMATION GUIDE

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### LAST UPDATED

This educational guide was last updated *October 3, 2025*.

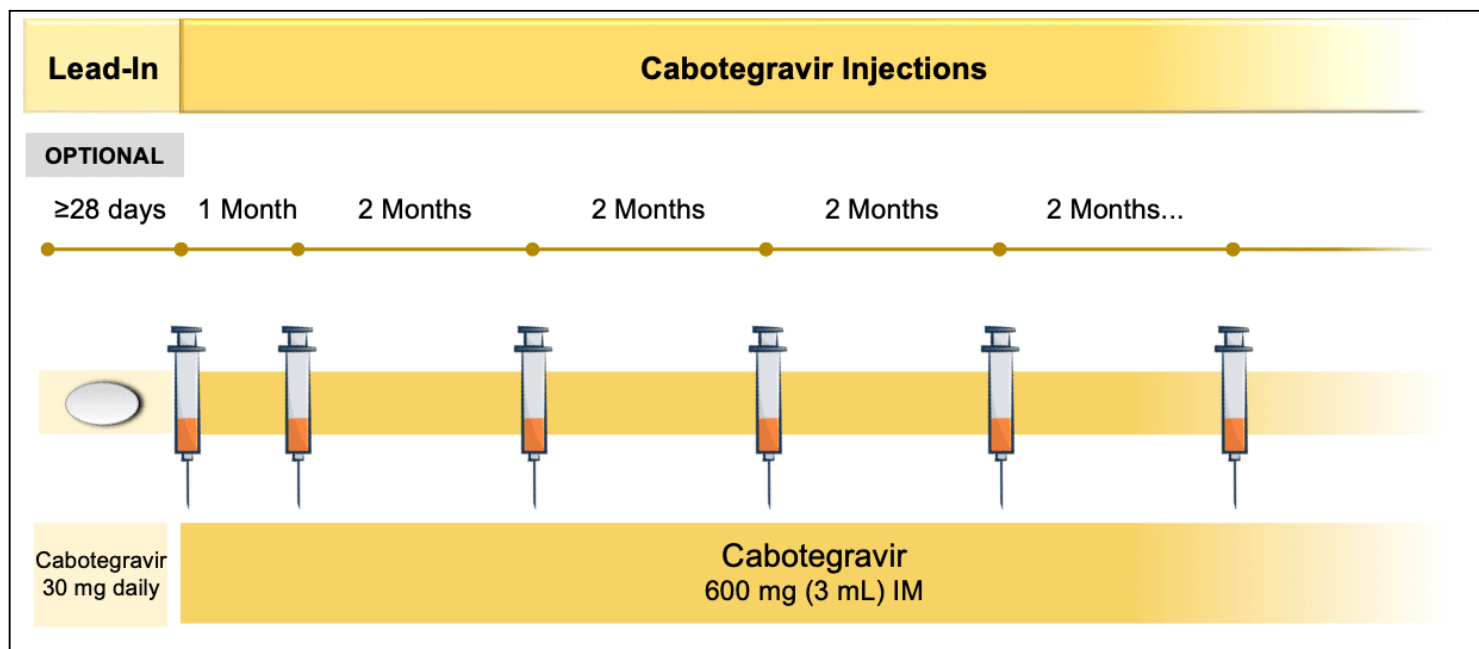
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**Figure 4 Long-Acting Injectable Cabotegravir (CAB-LA) Dosing Schedule**

Illustrator: David H. Spach, MD





## Figure 5 Exercise for Choosing HIV PrEP

**INSTRUCTIONS:** Review the scenario and question below and then select recommended or not recommended for each of the PrEP regimens shown. The choice of recommended or not recommended for each PrEP regimen should be based on whether it is recommended in the CDC 2021 HIV PrEP Clinical Practice Guidelines for the specific scenario provided. With all cases, assume the individual has a negative baseline HIV test.

Scenario 1 of 8

1

2

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4

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A 27-year-old man frequently has receptive and insertive anal sex with men. He was diagnosed with syphilis 2 weeks ago and is very interested in taking HIV PrEP. He has normal renal function.

HIV PrEP Regimens

For Each of the Regimens, Choose Recommended or Not Recommended for this Situation

Tenofovir DF-emtricitabine

Recommended

Not Recommended

Tenofovir alafenamide-emtricitabine

Recommended

Not Recommended


Injectable Cabotegravir

Recommended

Not Recommended

Submit

**Figure 6 HIV PrEP Tools for Clinicians: Medications**

 National HIV PrEP Curriculum

# Medications for HIV PrEP

## Read This

**To use this tool you will need to know:**

- 1) The patient's indication for HIV PrEP (sexual or injection drug use).  
If unknown, go to the Assessment section of this tool.
- 2) A recent value for estimated creatinine clearance.

The following medication abbreviations are used:

- TDF-FTC = tenofovir disoproxil fumarate-emtricitabine
- TAF-FTC = tenofovir alafenamide-emtricitabine
- CAB-LA = long-acting, injectable cabotegravir

Start Medications

Back to Menu

Table 1.

## Recommendations for HIV PrEP Medication Dosing in Persons with Renal Insufficiency

Estimated Creatinine Clearance	TDF-FTC	TAF-FTC	HIV PrEP Medication CAB-LA
≥60 mL/min	Normal Dosing	Normal Dosing	Normal Dosing
30-59 mL/min	Not recommended	Normal Dosing	Normal Dosing
15-29 mL/min (not on hemodialysis)	Not recommended	Not recommended	Normal Dosing
<15 mL/min (not on hemodialysis)	Not recommended	Not recommended	Unknown
<15 mL/min (on hemodialysis)	Not recommended	Normal Dosing <sup>†</sup>	Normal Dosing

Abbreviations: TDF-FTC = tenofovir disoproxil fumarate-emtricitabine; TAF-FTC = tenofovir alafenamide-emtricitabine; CAB-LA = cabotegravir; LEN-SQ = lenacapavir subcutaneous injection

\*Effects on the pharmacokinetics are unknown in persons with end-stage renal disease who are not on hemodialysis

<sup>†</sup>On days of dialysis, administer the dose after completion of hemodialysis

<sup>‡</sup>Since cabotegravir is >99% protein bound, hemodialysis is not expected to alter the exposure of cabotegravir

<sup>§</sup>Since lenacapavir is >99% protein bound, hemodialysis is not expected to alter the exposure of lenacapavir

Table 2.

**HIV PrEP Medications and Use in Specific Groups and Situations**

Group/Situation	TDF-FTC	HIV PrEP TAF-FTC
Men who have sex with men	Recommended	Recommended
Women who have sex with men	Recommended	Not Recommended*
Men who have sex with women	Recommended	Recommended
People who inject drugs	Recommended	Not recommended†
On demand option‡	Possible option‡	Not recommended
Adolescent boys (≥35 kg)	Recommended	Recommended
Adolescent girls (≥35 kg)	Recommended	Not recommended*

Abbreviations: TDF-FTC = tenofovir disoproxil fumarate-emtricitabine; TAF-FTC = tenofovir alafenamide-emtricitabine subcutaneous injection

\*At this time, the use of TAF-FTC is not FDA-approved or recommended by the CDC for the prevention of vaginal acquisition or reduction in risk for HIV acquisition in women who had biomarker evidence of taking at least a mean of 2 doses of TAF-FTC

†This HIV PrEP medication may be considered in people who inject drugs if there is an indication for use to prevent sexual transmission

‡The on-demand option applies only to men who have sex with men and only with use of TDF-FTC.

