

# **HIV PrEP Medications and Dosing Options**

This is a PDF version of the following document:Module 1:HIV PrEP FundamentalsLesson 3:HIV PrEP Medications and Dosing Options

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## Background

There are three medications approved by the United States Food and Drug Administration (FDA) for HIV preexposure prophylaxis (PrEP): oral tenofovir DF-emtricitabine (TDF-FTC), oral tenofovir alafenamideemtricitabine (TAF-FTC), and long-acting injectable cabotegravir (CAB-LA). These medications have unique characteristics, and clinicians should be familiar with appropriate indications and populations for use of these medications for HIV PrEP. The medications 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.

Watch the brief video below on **HIV PrEP: Mechanism of Action** (*8 minutes*) to better understand how HIV PrEP medications block HIV replication.

This lecture is part of our Mini-Lectures section.



# **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).
- **Dosing**: When used for HIV PrEP, the indicated dosing for TDF-FTC is one tablet once daily. Alternative dosing, such as on-demand (2-1-1) dosing, is not FDA-approved, but it can be considered among men who have sex with men (MSM) who request on-demand HIV PrEP.
- **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.[1,2]
- 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.
- 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.[3,4,5] In addition, small
  decreases in bone mineral density among persons taking TDF-based HIV PrEP have been shown to
  reverse after HIV PrEP discontinuation.[6,7,8] Serum lipid profiles are not adversely impacted by TDFFTC.

## 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. It is important to note that TAF-FTC is not indicated for receptive vaginal sex because effectiveness in this population has not been evaluated. Although the HIV PrEP indication for TAF-FTC does not exclude use for men at risk of sexual acquisition of HIV via insertive vaginal sex, it is important to note that TAF-FTC has not been studied as a prevention measure for insertive vaginal sex.
- **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.
- **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).
- 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.
- 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.[9,10] When used as daily HIV PrEP, TAF-FTC caused a light decrease in high density lipoprotein (HDL) levels, a slight increase in triglyceride levels, but no change in total cholesterol or low-density lipoprotein (HDL) levels.[9]

## Long-Acting Injectable Cabotegravir (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.
- **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 cabotegravir should be given on the last day of the oral lead-in (or within 3 days of completing the oral lead-in).
- **Formulation**: Injectable cabotegravir 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.
- **Food Requirements**: There are no food restrictions with CAB-LA. Oral cabotegravir can be taken with or without food.
- 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.
- **Side Effects**: Injection site reactions are the most common adverse events with CAB-LA.[<u>11,12,13</u>] In a randomized controlled trial of CAB-LA versus oral TDF-FTC for HIV PrEP, 81% of the participants in the CAB-LA arm reported an injection site reaction, with pain and tenderness being the most common symptoms.[<u>13</u>]

### Cabotegravir Guide

Review the Information Guide on *Long-Acting Injectable Cabotegravir for HIV PrEP* below (Figure 2) and answer the Check on Learning questions below.

- [Q] Cabotegravir Dosing
- [Q] Acceptable Ranges with Cabotegravir Dosing
- [Q] Missed Cabotegravir Dose[Q] What should you do at this point regarding his HIV PrEP?



# **Use of HIV PrEP Medications with Renal Insufficiency**

Among the three 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 (Figure 1). These recommendations are based on the prescribing information for TDF-FTC, TAF-FTC, and CAB-LA.

[Q] Use of Tenofovir DF-emtricitabine in Persons 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.[<u>10,14</u>] 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.[<u>14</u>] 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 ondemand HIV PrEP, several major guidelines recommend on-demand TDF-FTC as an HIV PrEP option for MSM.[10,15] There are no other medications that are FDA-approved or recommended for use as ondemand HIV PrEP.
- **Dosing Schedule with On-Demand HIV PrEP**: The recommended TDF-FTC dosing schedule for ondemand 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 (Figure 5) summarizes major indications for each of the three FDA-approved HIV PrEP medications and how the CDC recommends using these medications for HIV PrEP.

## **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 10 case scenarios in this interactive exercise. (Figure 6)



# **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.[10] 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 7). 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.



# Summary Points

- The FDA has approved three drugs for HIV PrEP usage: oral TDF-FTC, oral TAF-FTC, and CAB-LA. A negative HIV test is recommended prior to initiation of HIV PrEP.
- 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 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 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. There are no renal restrictions.
- 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 cisgender MSM and transgender women who have sex with men there are three recommended options for HIV PrEP: TDF-FTC, TAF-FTC, and CAB-LA.
- For cisgender women there are two recommended HIV PrEP options for preventing HIV acquisition via vaginal sex: TDF-FTC and CAB-LA. For persons who are pregnant, CAB-LA is not recommended.
- For people who inject drugs, TDF-FTC is the only recommended medication 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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#### Figure 1 Recommendations for HIV PrEP Medications in Persons with Renal Insufficiency

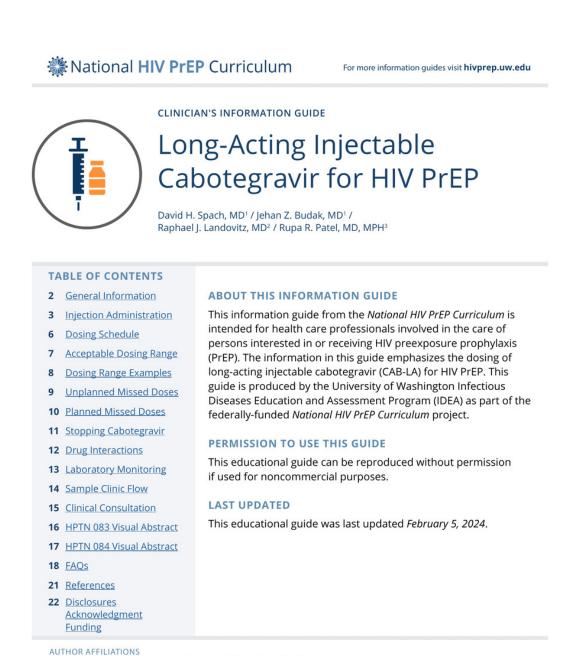
| Estimated                         | н               | IIV PrEP Medications                        | 5                                                     |
|-----------------------------------|-----------------|---------------------------------------------|-------------------------------------------------------|
| Creatinine Clearance (CrCl)       | TDF-FTC         | TAF-FTC                                     | CAB-LA                                                |
| CrCl ≥60 mL/min                   | Normal Dosing   | Normal Dosing                               | Normal Dosing                                         |
| CrCl 30-59 mL/min                 | Not recommended | Normal Dosing                               | Normal Dosing                                         |
| CrCl 15-29 mL/min                 | Not recommended | Not recommended                             | Normal Dosing<br>(Increased monitoring <sup>+</sup> ) |
| CrCl <15 mL/min (not on dialysis) | Not recommended | Not recommended                             | Normal Dosing<br>(Increased monitoring <sup>+</sup> ) |
| CrCl <15 mL/min (on dialysis)     | Not recommended | Normal Dosing*<br>(Give after hemodialysis) | Normal Dosing                                         |

Abbreviations: tenofovir DF-emtricitabine; TAF-FTC = tenofovir alafenamide-emtricitabine; CAB-LA = long-acting injectable cabotegravir \*If receiving hemodialysis, normal daily dosing is recommended, but on days of hemodialysis give after hemodialysis

\* Increased clinical monitoring for any potential cabotegravir-related adverse effects



#### Figure 2 Long-Acting Injectable Cabotegravir Guide



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<sup>2</sup> Division of Infectious Diseases / University of California, Los Angeles

<sup>3</sup> Whitman Walker Institute

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

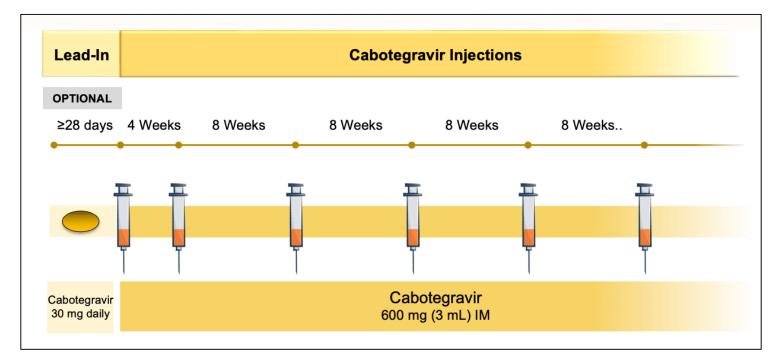


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#### Figure 4 Long-Acting Injectable Cabotegravir (CAB-LA) Dosing Schedule

Illustraton: David H. Spach, MD





#### Figure 5 HIV PreP Medications and Use in Specific Groups and Situations

These recommendations are based on the CDC 2021 Clinical Practice Guideline on Preexposure Prophylaxis for the Prevention of HIV Infection.

Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. December 2021:1-108.

| Group                                     | l           | HIV PrEP Medication | IS              |
|-------------------------------------------|-------------|---------------------|-----------------|
| Group                                     | TDF-FTC     | TAF-FTC             | Cabotegravir    |
| Cisgender men (who have sex with men)     | Recommended | Recommended         | Recommended     |
| Transgender women (who have sex with men) | Recommended | Recommended         | Recommended     |
| Cisgender women (who have sex with men)   | Recommended | Not Recommended     | Recommended     |
| Cisgender men (who have sex with women)   | Recommended | Recommended         | Recommended     |
| Persons who inject drugs                  | Recommended | Not Recommended     | Not Recommended |
| Persons who take on-demand HIV PrEP       | Recommended | Not Recommended     | Not Recommended |
| Adolescent boys weighing ≥35 kg           | Recommended | Recommended         | Recommended     |
| Adolescent girls weighing ≥35 kg          | Recommended | Not Recommended     | Recommended     |



## Figure 6 Exercise for Choosing HIV PrEP

| cenario <b>1</b> of <b>10</b> | 1 2                               | 3              | 4                  | 5 6            | 7            | 8           | 9          | 0   |          |                                |
|-------------------------------|-----------------------------------|----------------|--------------------|----------------|--------------|-------------|------------|-----|----------|--------------------------------|
|                               |                                   |                |                    |                |              | _           |            |     |          |                                |
| A 27-year-old cis             |                                   |                |                    |                |              |             |            |     | was diag | nosed with                     |
| syphilis 2 weeks              | ago and is ver                    | y interest     | ted in tak         | king HIV PrEP. | He has nor   | mal renal   | unction    |     |          |                                |
|                               |                                   |                |                    |                |              |             |            |     |          |                                |
|                               |                                   |                |                    |                |              |             |            |     |          |                                |
|                               |                                   |                |                    |                |              |             |            |     |          |                                |
| IV PrEP Regimens              | For Each of th                    | ne Regimen     | <b>ns</b> , Choose | Recommended    | or Not Recom | mended for  | this Situa | ion |          |                                |
| IV PrEP Regimens              | For Each of th                    | ne Regimen     | <b>ns</b> , Choose | Recommended of | or Not Recom | mended for  | this Situa | ion |          |                                |
|                               | For Each of th<br>F-emtricitabing | and the second |                    | Recommended o  |              |             | this Situa |     | jectable | Cabotegravir                   |
|                               |                                   | e              | Те                 |                | namide-emt   |             | this Situa |     |          | Cabotegravir<br>Not Recommende |
| Tenofovir DI                  | F-emtricitabin                    | e              | Те                 | nofovir alafer | namide-emt   | tricitabine | this Situa | Iņ  |          | 5                              |
| Tenofovir DI                  | F-emtricitabin                    | e              | Те                 | nofovir alafer | namide-emt   | tricitabine | this Situa | Iņ  |          | 5                              |



#### Figure 7 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:

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

The following medication abbreviations are used:

- TDF-FTC = tenofovir disoproxil fumarateemtricitabine
- TAF-FTC = tenofovir alafenamideemtricitabine
- CAB-LA = long-acting, injectable cabotegravir

## **Start Medications**

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