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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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).[1,2] 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 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.[1] 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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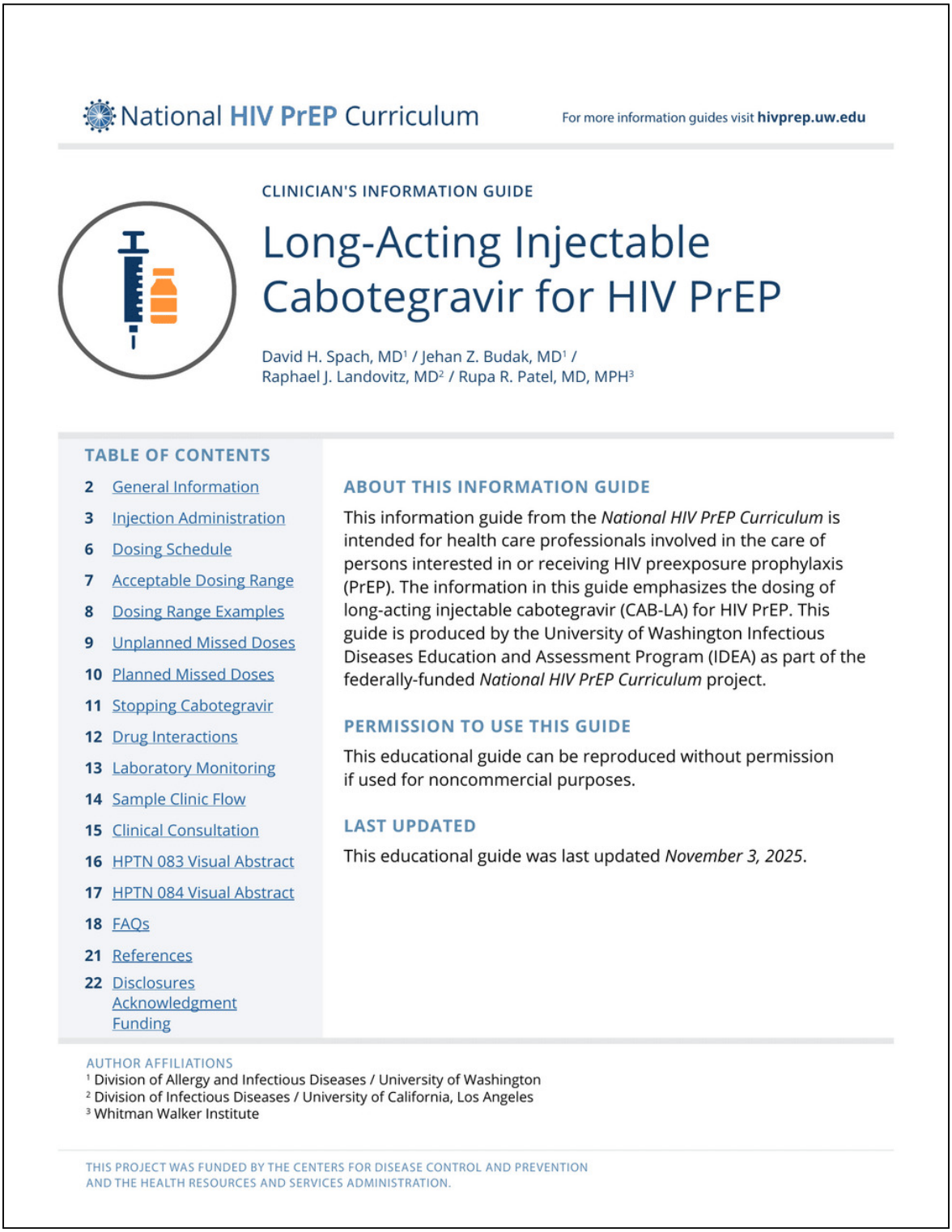
Figures

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.

PERMISSION TO USE THIS GUIDE

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Figure 2 Lenacapavir for HIV PrEP: Guide

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CLINICIAN'S INFORMATION GUIDE

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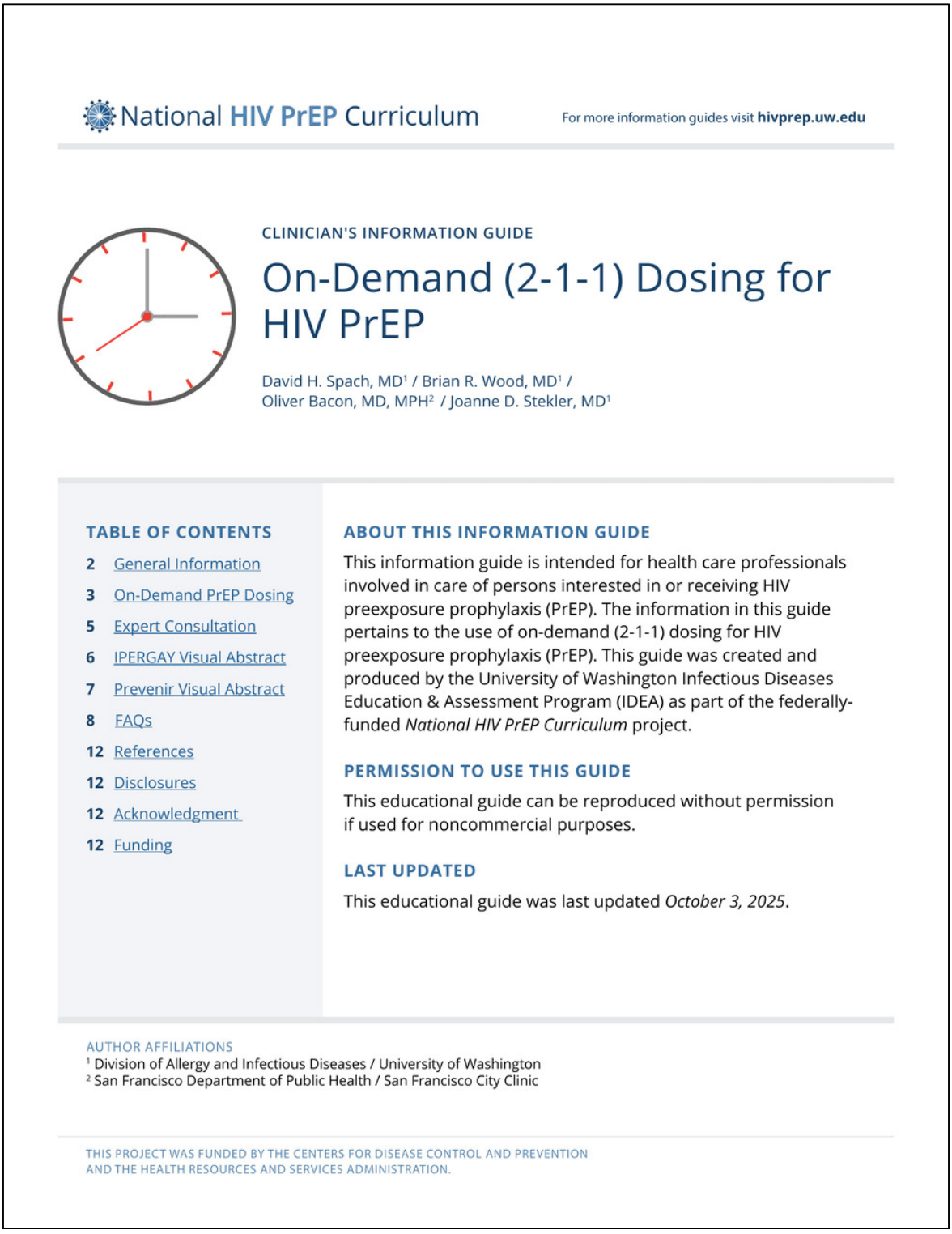
Figure 3 On-Demand (2-1-1) Dosing for HIV PrEP: Guide



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CLINICIAN'S INFORMATION GUIDE

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

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This information guide is intended for health care professionals involved in care of persons interested in or receiving HIV preexposure prophylaxis (PrEP). The information in this guide pertains to the use of on-demand (2-1-1) dosing for HIV preexposure prophylaxis (PrEP). This guide was created and produced by the University of Washington Infectious Diseases Education & Assessment Program (IDEA) as part of the federally-funded *National HIV PrEP Curriculum* project.

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

Illustraton: David H. Spach, MD

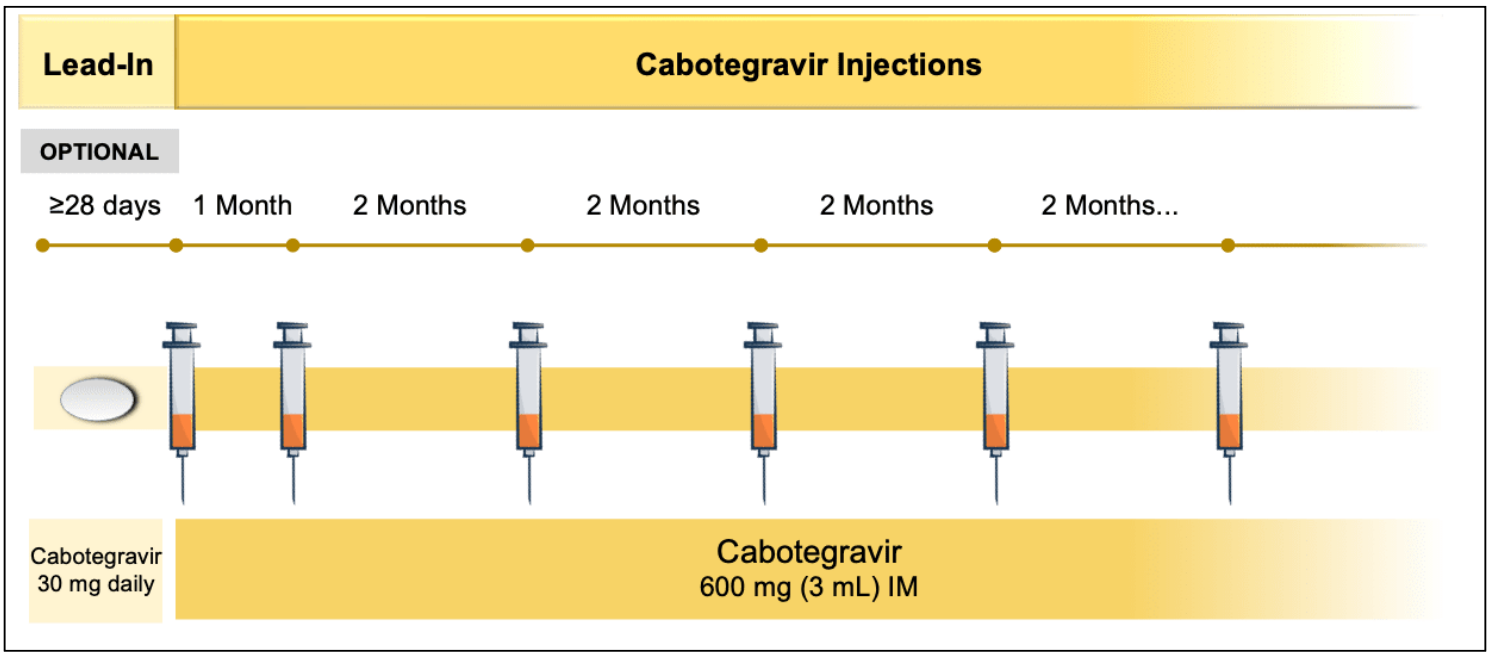

Figure 5 Exercise for Choosing HIV PrEP

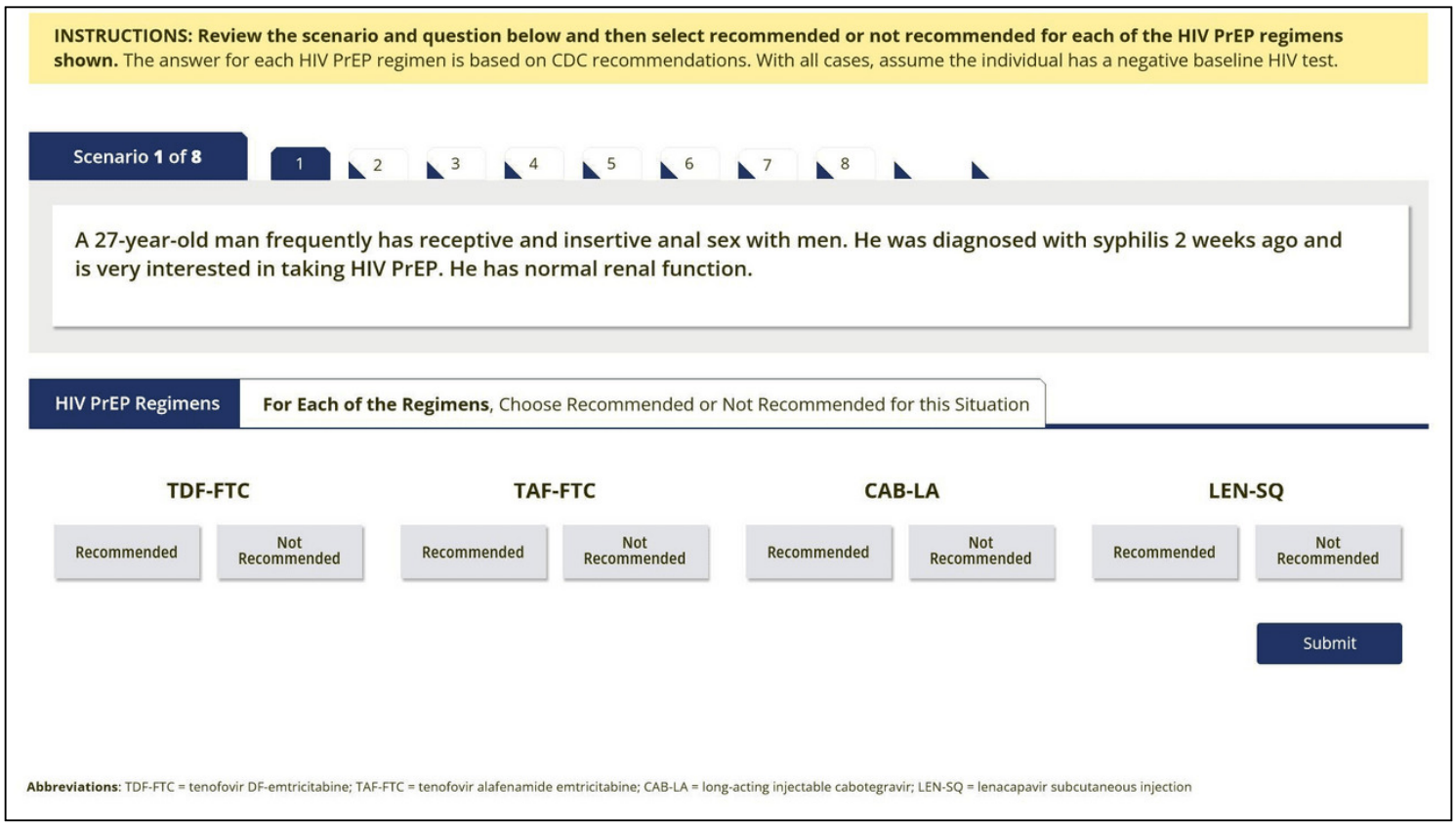

Figure 6 HIV PrEP Tools for Clinicians: Medications

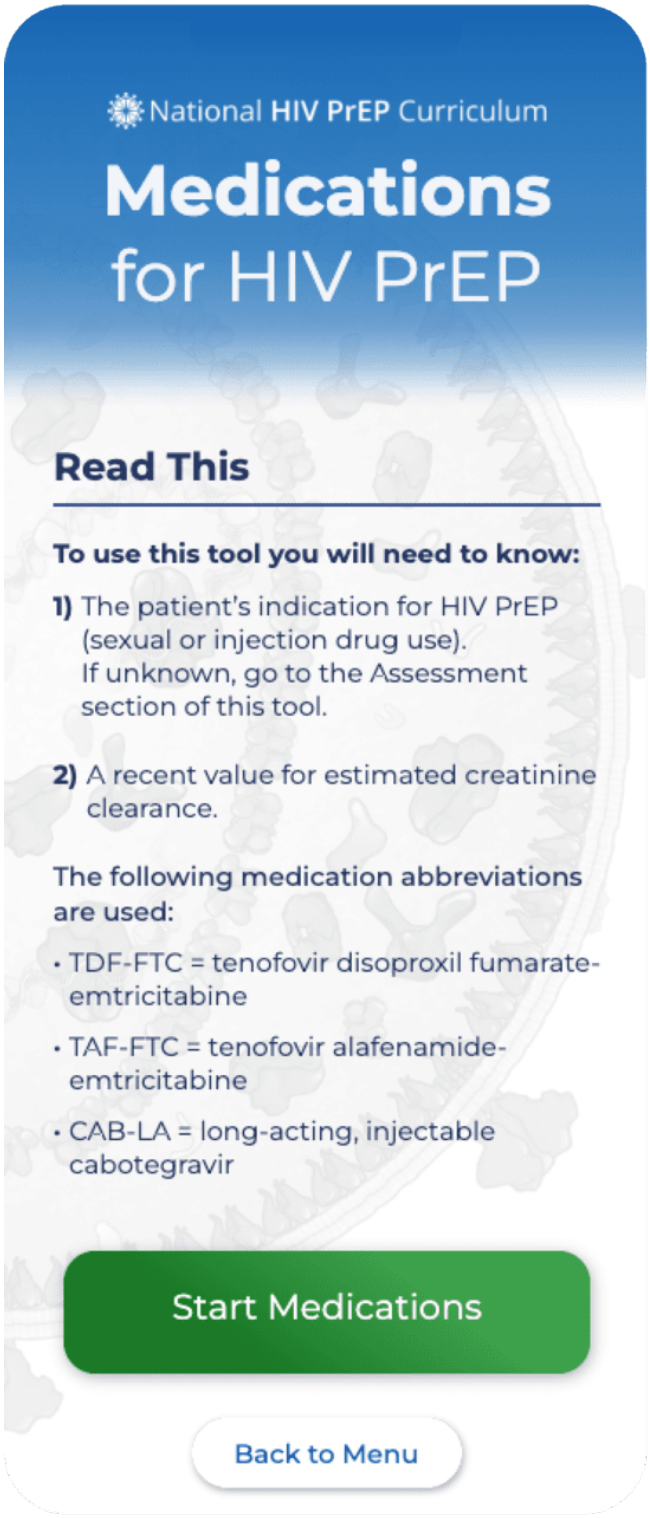

Table 1.

Recommendations for HIV PrEP Medication Dosing in Persons with Renal Insufficiency

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

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

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

[†]On days of dialysis, administer the dose after completion of hemodialysis

[‡]Since cabotegravir is >99% protein bound, hemodialysis is not expected to alter the exposure of cabotegravir

[§]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	HIV PrEP	
	TDF-FTC	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-emtricitabin
subcutaneous injection

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

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

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