AETC AIDS Education & Training Center Pacific

CDPH

Quick Clinical Guide:
HIV PrEP
Pre-Exposure Prophylaxis

Updated March 2019

Daily emtricitabine/tenofovir DF (Truvada®) is safe and effective for significantly reducing the risk of HIV infection in sexually active individuals (including adolescents) and people who inject drugs (PWID) when used consistently. This document is a brief "how-to guide," including medication coverage options for California state, and links to patient assistance programs for low-income patients. For resources and referrals, go to **PleasePrEPMe.org**. All web links are clickable in this document.

1. Identify patients who may benefit from PrEP

HIV-negative individuals, including adolescents, men who have sex with men (MSM), cis- and transgender women, who may benefit from PrEP include:

- People who ask for PrEP
- People with HIV-positive partners
- People with sexual exposures including: condomless anal sex, multiple sex partners, sex partners at high risk for HIV, or transactional sex (such as sex for money, drugs or housing)
- People who have had a bacterial sexually transmitted infection (STI)
- People who inject drugs (PWID) and people who use stimulants, such as methamphetamine, during sex

2. Discuss PrEP with your patient

Be present and listen. Ask about interest in and readiness for PrEP:

- What do you know about PrEP? Do you know anyone on PrEP?
- What makes you want to start PrEP? What do you hope PrEP will do for you?
- What barriers do you foresee? How long do you foresee being on PrEP?

Let them know what to expect and about the potential risks and benefits of PrEP. Important points include:

Potential side effects	• **Nausea or abdominal discomfort (~10%)**, which usually resolves in a few weeks • **Mild kidney dysfunction (<1%)**, which improves upon discontinuation of Truvada® • **Slightly decreased bone density**, but no increased risk of fractures • Many people on PrEP experience no side effects
Adherence	Adherence is correlated with higher effectiveness. Tailor adherence strategies to patient needs and lifestyle (pillbox, phone or online reminders, cell phone alarms, etc.). Many people who inject drugs are capable of adhering to PrEP. • For rectal exposures, no transmissions were seen in patients with detectable drug blood levels equivalent to ≥4 doses/week. Feminizing hormones may reduce tenofovir levels. For transgender women on hormones with rectal exposures, daily doses may be more important. • For vaginal/front exposures, no transmissions were seen in patients with detectable drug blood levels equivalent to 6-7 doses/week.
Risk of Resistance	Resistance to HIV medications can occur if acute HIV is not identified quickly while on PrEP. A negative HIV test result should be documented before initiating PrEP and every 3 months thereafter. The patient should report immediately to clinic if they develop symptoms compatible with acute HIV infection (fever with sore throat, rash, or headache).
Time to protection	**Time to protection varies by site of exposure** • Approximately 7 daily doses after starting PrEP in rectal tissue • Approximately 20 daily doses in cervico-vaginal tissue • Approximately 20 daily doses for blood exposures for people who inject drugs

6. Select PrEP Medication

There are two agents FDA-approved for PrEP, Truvada® and Descovy®, which are both safe and highly effective in clinical trials. There were no differences in adverse clinical outcomes such as broken bones or heart disease between people taking either drug. Choice may be limited by insurance coverage; Medi-Cal covers both.

PrEP medication	 **Truvada®** **Tenofovir disoproxil fumarate 300 mg + Emtricitabine 200 mg (F/TDF)**	Not for cisgender females  - males - transgender females **Descovy®** **Tenofovir alafenamide 25 mg + Emtricitabine 200 mg (F/TAF)**
Indications	Truvada® is approved for use for all adults and adolescents ≥35 kg with indications for PrEP.	Descovy® is approved for use for adults and adolescents ≥35 kg at risk for sexually acquired HIV, **excluding** individuals at risk only from receptive vaginal/front hole sex or only from injection drug use.
Dosing	1 pill once daily ~~- unless using a PrEP 2-1-1 schedule -~~	1 pill once daily
"On-Demand" PrEP: 2-1-1 dosing Note that while there is substantial published data supporting this strategy for MSM, it has not been reviewed by the FDA or recommended by the CDC. The International AIDS Society of the US (IAS-USA), World Health Organization (WHO), and European AIDS Clinical Society (EACS) all endorse the option of this dosing strategy.	**2-1-1 for MSM with anal exposures only:** 2 pills 2-24 hours before anal sex (24 hours before for optimal protection) - then 1 pill 24 hours after first dose - then 1 pill 24 hours after second dose. • If there is another exposure within 7 days of the last dose, take 1 pill 2-24 hours before anal sex, then 1 pill 24 hours after first dose, then 1 pill 24 hours after second dose. • If there are continued daily sexual exposures, continue 1 pill daily until 48 hours has passed since last sexual encounter. For a detailed 2-1-1 guide, go to: tinyurl.com/HIVPrEP211.	The PrEP 2-1-1 dosing schedule is **not** recommended for use with Descovy® outside of a clinical trial.
Side effects	Generally safe and well tolerated • Headache (7%) and abdominal discomfort (3%), which often resolve in a few weeks • Small decrease in eGFR, which improves upon discontinuation of Truvada® • Slightly decreased bone density, but no increased risk of fractures	Generally safe and well tolerated • Abdominal discomfort, nausea (5%) and headache (2%), which often resolve in a few weeks • Small increase in LDL cholesterol • Slight increase in body weight
Other notes	Estimated GFR or CrCl by serum labs should be ≥60 ml/min (Cockcroft-Gault) to safely use Truvada®. A generic form of Tenofovir disoproxil fumarate + Emtricitabine (F/TDF) is anticipated in October 2020.	Estimated GFR or CrCl by serum labs should be ≥30 ml/min (Cockcroft-Gault) to safely use Descovy®.

- Provide adherence counseling and anticipatory guidance about common side effects.
- Discuss patient strategies for daily adherence.
- Counsel patients on risk reduction using condoms with PrEP to decrease transmission of STIs.

- Check for Hep B + Hep C [redacted]

Table 1a: Summary of Clinician Guidance for **Daily Oral PrEP Use**

	Sexually-Active Adults and Adolescents[1]	**Persons Who Inject Drug[2]**
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply (Cisgender females) OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

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Do not use if hx of depression, or receiving medication for seizures or TB

Table 1b: Summary of Clinician Guidance for **Cabotegravir Injection PrEP Use**

	Sexually-Active Adults	**Persons Who Inject Drugs[1]**
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o **Initial dose** o **Second dose 4 weeks after first dose (month 1 follow-up visit)** o **Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)**	
Follow-up care	**At follow-up visit 1 month after first injection** • HIV Ag/Ab test and HIV-1 RNA assay **At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:** • Bacterial STI screening[2] for MSM and transgender women who have sex with men[2] – oral, rectal, urine, blood **At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:** • Bacterial STI screening[1] for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood **At follow-up visits at least every 12 months (after the first injection) provide the following:** • Assess desire to continue injections for PrEP • Chlamydia screening for heterosexually active women and men – vaginal, urine **At follow-up visits when discontinuing cabotegravir injections provide the following:**	

[1] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[2] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs