# **Pre-Exposure Prophylaxis (PrEP)**

Prepared by Rachel Porth, M22, Tufts University School of Medicine (December 2019)

Truvada is the brand name for a pre-exposure prophylaxis (PrEP) oral antiretroviral medication consisting of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC). It works by blocking HIV reverse transcriptase, which prevents the conversion from RNA to DNA. It can be prescribed by any licensed prescriber. The purpose of the medication is to prevent someone who is HIV-negative from getting HIV. Once someone starts taking Truvada it takes 7 days to reach maximum protection from HIV for receptive anal sex, and 20 days for receptive vaginal sex and injection drug use.

## Guidelines: USPSTF grade A recommendation to persons at high risk of HIV acquisition

High Risk individuals who should be assessed for PrEP include:

- 1 in 4 sexually active gay and bisexual adult men without HIV
- 1 in 5 adults without HIV who inject drugs
- 1 in 200 sexually active heterosexual adults without HIV

## **CDC Indications:**

Recommended Indications for PrEP		
Men Who have Sex with Men	Hetorosexual Women and Men	People Who Inject Drugs
<ul> <li>Adult or adolescent male weighing at least 35kg (77 lbs)</li> <li>Without acute or established HIV infections</li> <li>Any male sex partners in past 6 months (if also sex with women, see next box)</li> <li>Not in a monogamous partnership with a recently tested, HIV-negative man</li> </ul>	<ul> <li>Adult or adolescent person weighing at least 35kg (77 lbs)</li> <li>Without acute or established HIV infections</li> <li>Any sex with opposite sex partners in past 6 months</li> <li>Not in a monogamous partnership with a recently tested, HIV-negative partner</li> <li>AND at least one of the following</li> <li>Is a man who has sex with both women and men</li> </ul>	<ul> <li>Adult or adolescent male weighing at least 35kg (77 lbs)</li> <li>Without acute or established HIV infections</li> <li>Any sex with opposite sex partners in past 6 months</li> <li>Any injection of drugs not prescribed by a clinician in past 6 months</li> </ul>
AND at least of the following	(behaviorally bisexual) [also evaluate indications for PrEP use by previous box criteria]	AND at least one of the following
Any anal sex without condoms (receptive or insertive) in past 6 months	<ul> <li>infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)</li> </ul>	<ul> <li>Any sharing of injection or drug preparation equipment in past 6 months</li> </ul>

- A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIVpositive partner
- A bacterial STI (syphilis, gonorrhea in women or men diagnosed or reported in past 6 months)
- risk of sexual acquisition (also evaluate by criteria in previous boxes)

### **Effectiveness:**

- Sexual transmission route: ~99% effective when taken daily or consistently (at least 4 times per week) (CDC 2019)
  - o 99% effective for 7 doses per week (Anderson 2012)
  - o 96% for 4 doses per week (Anderson 2012)
  - o 76% for 2 doses per week (Anderson 2012)
- Injection drug transmission route: 74-84% effective when taking tenofovir alone consistently
  - Efficacy may be greater for the two-drug oral therapy and if used daily
- Safe in pregnant and breastfeeding women
- Efficacy has not been established in patients co-infected with HBV and HIV-1
  - Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected and discontinue therapy

### Downsides:

- Must be taken daily to be effective
- Truvada doesn't protect against other STIs, such as gonorrhea or chlamydia. Condoms should still be used.
- Follow up with a doctor is needed every 3 months for HIV/STI/pregnancy testing and serum creatinine and calculated creatinine clearance (at 3 months after initiation, then every 6 months)
- Cannot be taken by people with renal insufficiency (creatinine clearance must be >60) because the medication is eliminated by the kidneys

### Potential side effects:

- Common: rash (7%), abdominal pain (4%), diarrhea (9%), nausea (9%), serum amylase raised (8%), backache (5% or greater), myalgia (5% or greater), dizziness (8%), headache (6-7%), insomnia (5%), peripheral neuropathy (5%), depression (9%), dream disorder (10%), pneumonia (5%), fatigue (9%)
- **Serious:** Lactic acidosis, pancreatitis, hepatomegaly, with steatosis, hepatoxicity, reactivation of hepatitis B viral hepatitis, immune reconstitution syndrome, fracture of bone, osteopenia, rhabdomyolysis, Fanconi syndrome, renal failure, renal impairment

### Conclusion:

Truvada is effective at preventing HIV infection if taken daily. However, it does require monitoring by a physician, does not prevent other STIs, and may come with potential side effects. A patient who is healthy, has no history of HIV infection, and is willing to comply with medication dosing and physician follow up should be assessed for Truvada.

### **Additional Resources:**

Click on this link for a short PrEP quickstart guide for yourself, or your preceptor.

Click on this link for a slightly more in-depth guide to prescribing PrEP, and frequency of follow up visits and testing.

### Sources:

- -Anderson, P. L., Glidden, D. V., Liu, A., Buchbinder, S., Lama, J. R., Guanira, J. V., ... & Veloso, V. G. (2012). Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Science translational medicine*, *4*(151), 151ra125-151ra125.
- -Centers for Disease Control and Prevention. (2019). Prescribe PrEP Pre-Exposure Prophylaxis FAQs for the Health Care Professional. Retrieved from <a href="https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-prep-faq.pdf">https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-prep-faq.pdf</a>
- -DynaMed [Internet]. Ipswich (MA): EBSCO Information Services. 1995 . Record No. *T907614*, *Emtricitabine/Tenofovir*; [updated *2018 Nov 06*, cited 2019 Oct 21]. Available from https://www.dynamed.com/topics/dmp~AN~*T907614*. Registration and login required.