

VA



U.S. Department of Veterans Affairs

Veterans Health Administration
PBM Academic Detailing Service

A QUICK REFERENCE GUIDE (2017)

Pre-Exposure Prophylaxis

Reducing Human Immunodeficiency Virus
(HIV) Risk with Pre-Exposure Prophylaxis (PrEP)



VA PBM Academic Detailing Service

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Real Patient Results

Your Partner in Enhancing Veteran Health Outcomes

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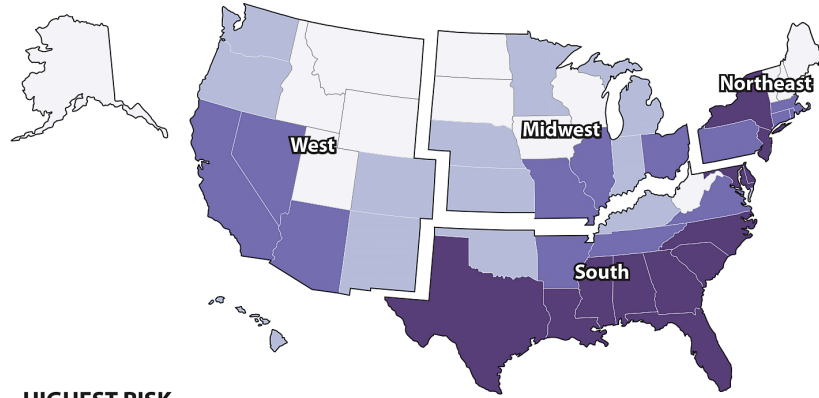
Abbreviations Used in this Document

Abbreviation	Definition
FTC	Emtricitabine
HIV	Human immunodeficiency virus
IDU	Injection drug user
MSM	Men who have sex with men
NSAIDs	Non-steroidal anti-inflammatory drugs
PrEP	Pre-Exposure Prophylaxis; Note: Currently only one prescription is FDA approved for PrEP and thus PrEP may be used interchangeably with TDF/FTC in this document
STI	Sexually transmitted infection
TDF	Tenofovir* disoproxil fumarate
TDF/FTC	Combination pill containing tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg; brand name: Truvada®

*Tenofovir comes in two forms: tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide fumarate (TAF). All reference of tenofovir in this document correspond to TDF unless otherwise specified. TAF and TDF are not interchangeable. TAF containing preparations should not be used for PrEP.¹

Lifetime Risk of HIV Diagnosis by State

Consider PrEP as another resource to prevent HIV infection. In areas of the United States with higher lifetime risk of HIV infection², like Alabama and Delaware, this can be even more important.



HIGHEST RISK

LOWEST RISK

State	One in "n"	State	One in "n"	State	One in "n"	State	One in "n"
District of Columbia	13	Nevada	98	Michigan	167	West Virginia	302
Maryland	49	Illinois	101	Oklahoma	168	Wisconsin	307
Georgia	51	California	102	Kentucky	173	Iowa	342
Florida	54	Tennessee	103	Indiana	183	Utah	366
Louisiana	56	Pennsylvania	115	Washington	185	Maine	373
New York	69	Virginia	115	Colorado	191	Alaska	384
Texas	81	Massachusetts	121	New Mexico	196	South Dakota	402
New Jersey	84	Arizona	138	Hawaii	202	New Hampshire	411
Mississippi	85	Connecticut	139	Oregon	214	Wyoming	481
South Carolina	86	Rhode Island	143	Minnesota	216	Vermont	527
North Carolina	93	Ohio	150	Kansas	262	Idaho	547
Delaware	96	Missouri	155	Nebraska	264	Montana	578
Alabama	97	Arkansas	159			North Dakota	670

Source: Centers for Disease Control and Prevention

HIV Prevention Strategies



Safe Sex

- Use condoms



Avoid Sharing Needles

- Promote needle exchange programs



Use HIV PrEP

- Lowers risk of HIV infection by >90%

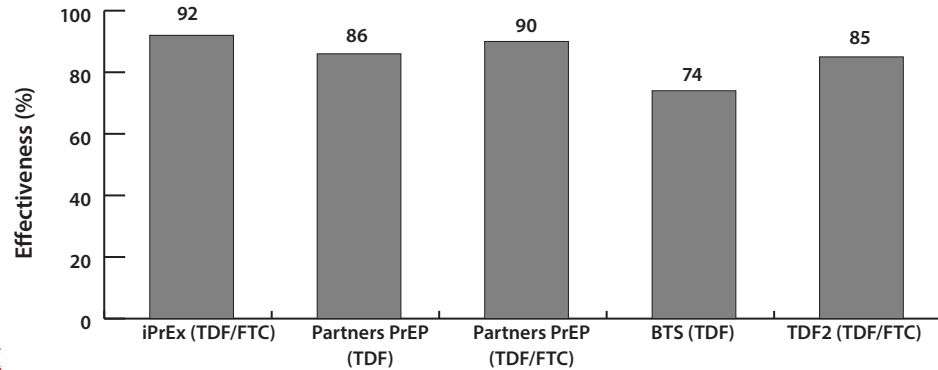
Patients Highly Adherent to PrEP Can Reduce Their Risk of HIV Infection by Over 90%^{3,*}

1 pill a day



Helps keep HIV away!

Efficacy by Blood Detection of Tenofovir



Trials of oral TDF and TDF/FTC show that adherence is very important to the effectiveness of PrEP. When tenofovir levels were measured, having detectable levels directly correlated to a lower risk of acquiring HIV. iPrEx – Preexposure Prophylaxis Initiative Trial in MSM comparing TDF/FTC to placebo. Partners PrEP – Trial for the prevention of HIV in uninfected partner in HIV-discordant heterosexual couples comparing TDF, TDF/FTC and placebo. BTS – Bangkok Tenofovir Study comparing TDF to placebo for HIV prevention among Intravenous drug users (IDUs). TDF2 – Study in heterosexual men and women comparing TDF/FTC to placebo.

Steps to Prescribing PrEP

Prescribe PrEP to Veterans at risk for HIV infection with a current negative HIV status and with appropriate renal function.

Assess HIV Risk

- Discuss sexual health
- Discuss injection drug use

Indications for PrEP

- All Veterans who have sex or share injection equipment with HIV infected or HIV unknown people should be offered PrEP
- See pages 10–11 for other risk groups

Assess for Current HIV Infection

- Order 4th generation testing
- Check for signs/symptoms of acute HIV infection
- Do NOT use PrEP in Veterans with signs/symptoms of acute HIV infection or if they test positive for HIV

Check Other Baseline Labs

- Creatinine Clearance
- STIs
- Pregnancy Status
- Hepatitis B/C

Prescribe PrEP

- Tenofovir 300 mg/Emtricitabine 200 mg
- Take 1 tablet by mouth daily
- Limit to no more than 90 days supply
- Adherence determines effectiveness

Follow up

- Every 3 Months: HIV Status
- Every 6 Months: STIs & Creatinine Clearance
- Every 1 Year: Reassess need for PrEP
- Every 2–3 Years: Osteoporosis screening



Key Questions When Taking a Sexual Health History: The Five P's⁴

- Partners
 - Do you have sex with men, women, or both?
 - In the past 6 months, with how many partners have you had unprotected sex?
 - Is it possible that any of your sex partners in the past year had sex with someone else while they were still in a sexual relationship with you?
 - Do you know the HIV status of your partner(s)?
- Practices
 - Can you describe the type of sex you have with your partner(s)?
 - Do you use condoms, dental dams, rubber gloves, or other types of protection? If not, why not? If sometimes, in what situations do you use protection?
 - Have you ever had sex in exchange for something you needed (e.g., food, shelter, money)?
 - Is there anything else I should know about your sexual practices?

continued from page 8 (Key Questions When Taking a Sexual Health History: The Five P's)

- Protection from sexually transmitted infections (STIs)
 - ☑ Are you concerned about getting an STI?
 - ☑ How do you protect yourself from STIs and HIV?
- Past history of STIs
 - ☑ Have you ever had an STI?
 - ☑ Have any of your partners had STIs?
- Pregnancy
 - ☑ What are your plans regarding pregnancy?
 - ☑ What (if anything) are you doing to prevent pregnancy?



Key Questions to Discuss Injection Drug Use

- Have you ever injected drugs that were not prescribed to you by a health care provider?
- If yes:
 - When did you last inject drugs that were not prescribed to you?
 - In the past 6 months, have you injected using needles, syringes, or other drug preparation equipment that had already been used by another person?
 - In the past 6 months, have you been in a methadone, buprenorphine/naloxone, or other medication based drug treatment program?

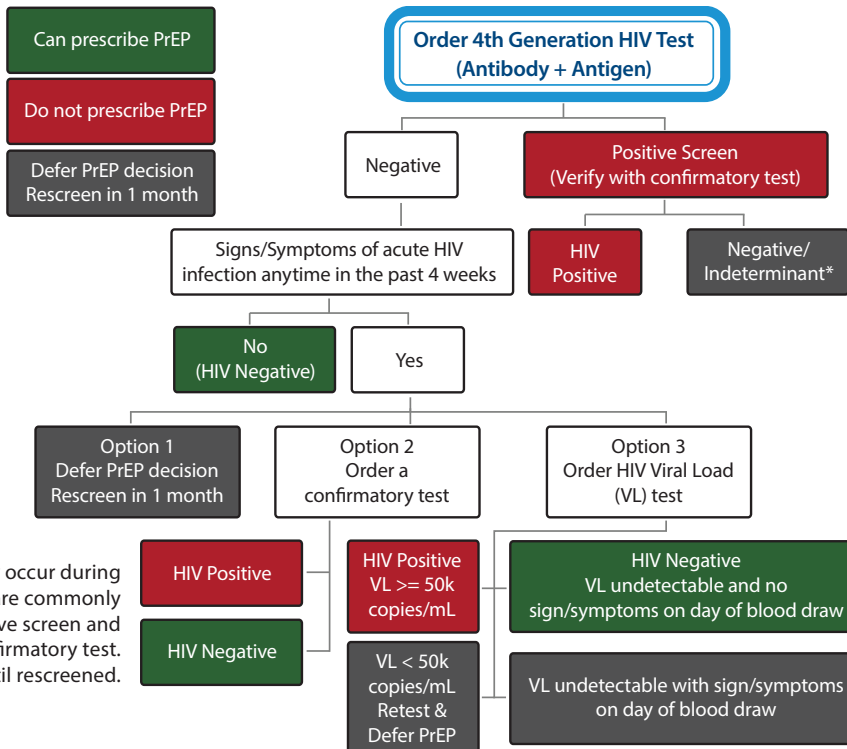


Injection Drug Use & Risky Sexual Practices are CDC Recommended Indications for PrEP⁵

CDC Recommended Indications for PrEP⁵


Component	Recommendation
Veterans who have sex or share injection equipment with HIV infected partner(s) should be offered PrEP	
Risk Assessment/ Indications (based on the past 6 months)	<ol style="list-style-type: none">1. Adult MSM with partner(s) without recently tested HIV-negative status<ul style="list-style-type: none">• Any anal sex without condoms• Sexually transmitted infection2. Heterosexually active women and men<ul style="list-style-type: none">• Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at increased risk (e.g., IDU, bisexual male partner (review MSM criteria))3. Injection drug users<ul style="list-style-type: none">• Treatment in a clinic providing medication assisted treatment (e.g., methadone, buprenorphine/naloxone (Suboxone))• Shared injection equipment

Recommended Laboratory HIV Testing Algorithm for Serum and Plasma Specimens



*Indeterminate results may occur during seroconversion and are commonly associated with a positive screen and negative or unknown confirmatory test. Defer PrEP decision until rescreened.

Who Should Be Prescribed PrEP?

HIV TESTING	Veterans should be confirmed HIV negative prior to offering PrEP.
NEG (-) RESULTS	Initiate PrEP within 1 week of negative results in Veterans who lack signs and symptoms of acute HIV infection.
	Signs and symptoms of acute HIV infection <ul style="list-style-type: none">• Fever• Fatigue• Swollen glands• Sore throat• Rash

Baseline Laboratory Tests

Status	Labs	Action
HIV	4th Generation HIV Test (HIV-1/2 antigen/antibody combination immunoassay)	Initiate PrEP within 1 week of negative HIV results in Veterans at risk for HIV and who lack signs and symptoms of acute HIV infection.
Renal Function	Serum Creatinine	Consider PrEP only in Veterans with CrCl \geq 60 mL/min.
Hepatitis B	Hepatitis B surface antigens (HBsAg) Hepatitis B core antibodies (Anti-HBc) Hepatitis B surface antibodies (Anti-HBs)	If HBsAg is positive, consider referring for HBV treatment. If Anti-HBs is positive, document immunity. If Anti-HBs is negative, begin HepB vaccination series.
Pregnancy	Pregnancy Test (urine beta-HCG)	If pregnant or intending to conceive with an HIV infected spouse, refer to an ID or fertility specialist.

*Use Nucleic Acid Amplification Tests (NAAT) whenever possible. Swab samples should be obtained from all anatomically exposed sites (e.g. genital, rectal, pharyngeal).

continued from page 14 (Baseline Laboratory Tests)

Status	Labs	Action
Sexually Transmitted Infections (STIs)	Syphilis (RPR or FTA) Gonorrhea* Chlamydia*	Treat STIs or refer for treatment; does not impact PrEP initiation.
Hepatitis C	HCV antibody (HCV Ab)	If positive, check HCV RNA viral load. If viral load is detectable, refer for evaluation and/or treatment of chronic HCV infection.

*Use Nucleic Acid Amplification Tests (NAAT) whenever possible. Swab samples should be obtained from all anatomically exposed sites (e.g. genital, rectal, pharyngeal).

Prescribing PrEP (TDF/FTC)

Day Supply:

- Initiation: 30 days
- Maintenance: Up to 90 days

Contraindications:

- Positive or Unknown HIV Status
- CrCl < 60 mL/min
- Prior severe reaction to TDF/FTC

Pregnancy:

- PrEP can be safely used during pregnancy and patients should be referred to an ID or fertility specialist

Hepatitis B:

- Veterans with hep B may experience hepatitis flare upon discontinuation of PrEP

FOR _____ DATE _____

R_x

ADDRESS _____

**Truvada (Tenofovir 300 mg / Emtricitabine 200 mg)
Take 1 tablet by mouth daily # 30**

Refills: 0

DR. _____ DR. _____

SUBSTITUTION PERMITTED

DISPENSE AS WRITTEN

DEA NO. _____

Drug Interactions Between TDF/FTC and Other Medications⁶

Medication	TDF/FTC
Medication Assisted Therapy (MAT): <ul style="list-style-type: none"> • Buprenorphine • Methadone • Naltrexone 	<ul style="list-style-type: none"> • No significant effect • No dosage adjustment necessary
Oral contraceptives	<ul style="list-style-type: none"> • No significant effect • No dosage adjustment necessary
Drugs affecting renal function: <ul style="list-style-type: none"> • Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir • Aminoglycosides • High-dose or multiple NSAIDs 	Pharmacology: <ul style="list-style-type: none"> • TDF/FTC is excreted by the kidneys via both glomerular filtration & active tubular secretion • Competition for active tubular secretion may increase concentrations of either agent(s) such as those listed to the left Monitor for dose-related renal toxicities

Patient Counseling for PrEP

Component	Recommendation
Side Effects	<p>Side effects are minimal but may include the following:</p> <ul style="list-style-type: none">• Headache and nausea (usually resolves after first few weeks)• Renal function decline (~3–5%)• Bone mineral density decline (1–3%) <p>Note: Usually returns to baseline upon discontinuation of therapy</p> <p>Rare/severe: Lactic Acidosis/Severe Hepatomegaly with Steatosis; Fanconi's syndrome</p>
Key Talking Points	<ul style="list-style-type: none">• Most effective (>90%) when taken daily; not just after sex• Other STIs can still be acquired• Greatly reduces the risk of HIV infection when combined with other risk reduction practices (e.g., condoms & clean needle exchange)• Generally well tolerated medication• Continue PrEP as long as high risk behaviors are practiced• Re-evaluate the need for PrEP when behaviors change and/or annually• Routine monitoring needs (see Monitoring section)• Consider seeking community treatment for partners

Monitoring Veterans on PrEP⁵

Every Visit	Every 3 Months	Every 6 Months
<p>Screen for Substance Use Disorder and refer as necessary or consider managing in Primary Care if preferred by Veteran</p> <ul style="list-style-type: none"> • Consider UDS <p>Provide general risk reduction counseling</p> <p>Assess Adherence to PrEP</p> <ul style="list-style-type: none"> • Review fill history • Ask the Veteran how he/she reminds him/herself 	<p>Check HIV Status</p> <ul style="list-style-type: none"> • 4th gen. test for both antibodies & antigens • Assess for s/sxs of acute HIV infection <ul style="list-style-type: none"> - fever, fatigue, swollen glands, sore throat, rash <p>Order Pregnancy Test:</p> <ul style="list-style-type: none"> • Urine beta-HCG 	<p>Test for STIs:</p> <ul style="list-style-type: none"> • Syphilis (RPR/FTA) • Gonorrhea* • Chlamydia* <p>*Testing should utilize Nucleic acid amplification tests (NAAT)</p> <p>Order Serum Creatinine: Consider more frequently in Veterans with additional risks (CKD, HTN, DM, Age >50)</p>
<p>Every Year: Re-Evaluate the Need for PrEP and Test for HCV in Patients with IVDU</p>		
<p>Every 2–3 Years: Osteoporosis Screening</p>		



References

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4. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(3):1-137.
5. Centers for Disease Control and Prevention. *Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014*. Centers for Disease Control; May 2014 2014.
6. Truvada(R) [package insert]. Gilead Sciences, Inc., Foster City, CA; April 2017.

U.S. Department of Veterans Affairs

This reference guide was created to be used as a tool for VA providers and is available to use from the Academic Detailing SharePoint. These are general recommendations only; specific clinical decisions should be made by the treating provider based on an individual patient's clinical condition.

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