Pre-Exposure Prophylaxis

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

VA

U.S. Department of Veterans Affairs

Veterans Health Administration

PBM Academic Detailing Service

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A VA Clinician's Guide

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Take-home Points

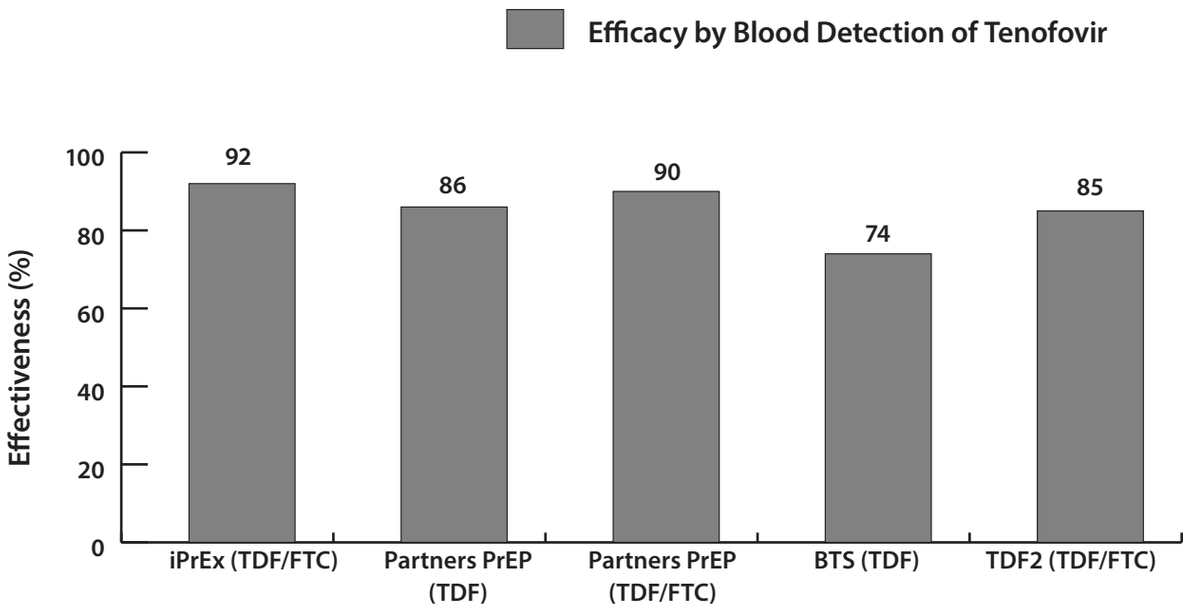
Pre-exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) is an effective way for people who are at high risk for human immunodeficiency virus (HIV) infection – but do not have HIV – to prevent HIV infection.

The FDA approved medication for PrEP consists of:

- Tenofovir* (TDF) 300 mg and emtricitabine (FTC) 200 mg (Truvada®)
- Combined into a single tablet taken once daily
- Consistent daily use of this medication can greatly reduce the risk of HIV-1 infection in Veterans when used in combination with other preventative measures such as condoms, clean needles, and other practices

Figure 1. PrEP Adherence Determines Effectiveness of Protection[1–6]



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.

HIV PrEP lowers risk of HIV infection by >90%

PrEP is one part of a comprehensive strategy to prevent HIV

- Safer sexual practices
- Barrier methods (e.g., condoms)
- Needle exchange program(s) where available

*Tenofovir currently 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 preparations should not be used for PrEP.[7]

PrEP Utilization is Increasing in the Department of Veterans Affairs (VA)

Figure 2. Between July 2012 and June 2017, TDF/FTC Prescribing Rose Among Men in the VA[8]

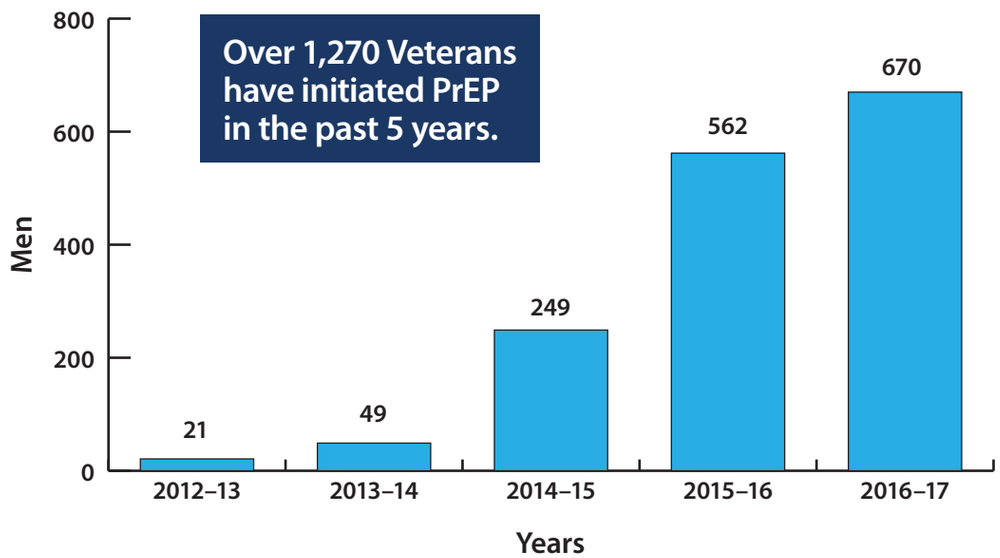
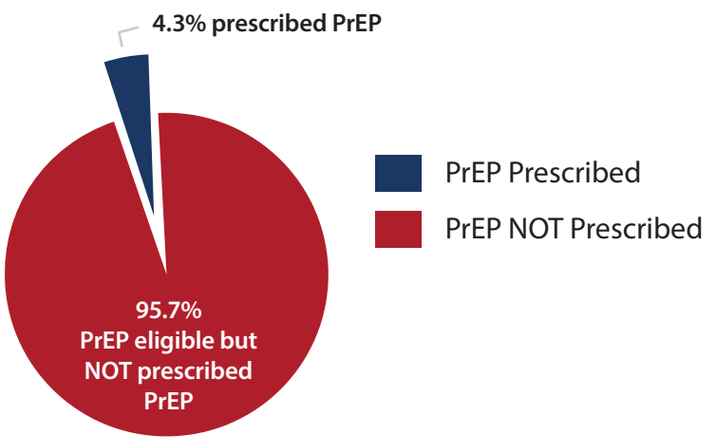


Table 1. Characteristics of Veterans in VA Prescribed PrEP[8]

VA Prescribed PrEP	
Veteran Characteristics	**Percent**
Male	97
White	66
Reside in Urban Areas	88
History of ≥1 Mental Health Diagnosis	75
Age (mean)	41 years old
Prescribing Facility Characteristics	**Percent**
West Coast	35
East Coast	21
Tertiary Care Facilities	64

Opportunities for PrEP Continue to Outpace Utilization

Figure 3. Over 1.2 million People in the US Could Benefit from PrEP[9,10]



Over 1.2 million people considered eligible for PrEP include:

- 492,000 men who have sex with men (MSM)
- 624,000 heterosexual men and women
- 115,000 injection drug users (IDU)

Ensure Equality in Offering PrEP

Despite the greater percentage of African Americans who are diagnosed with HIV, PrEP is predominantly used by whites. Ensure that all patients at high risk for HIV, especially men who have sex with men (MSM), are offered PrEP when appropriate.

Figure 4. Ethnic Groups with the Highest Rates of New HIV Infections are not Receiving Enough PrEP[9]

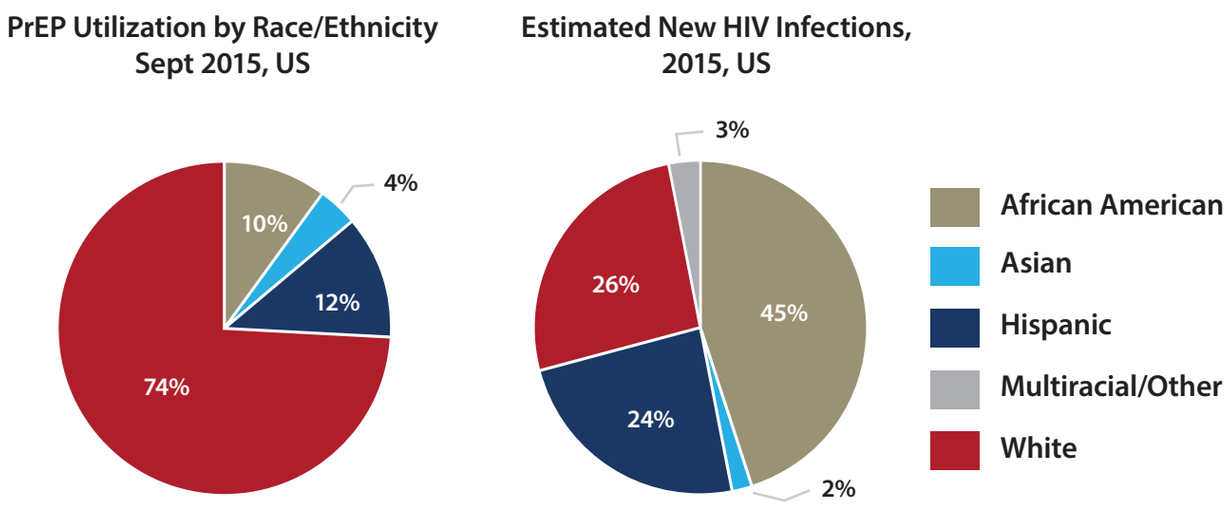
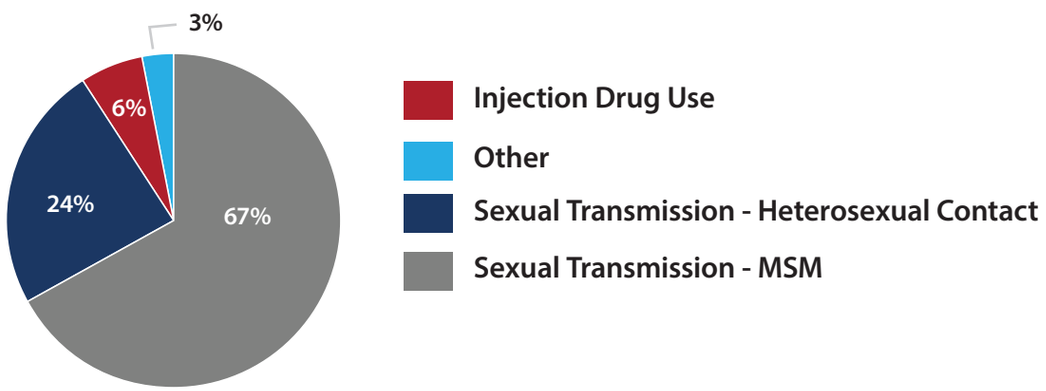


Figure 5. Routes of HIV Transmission

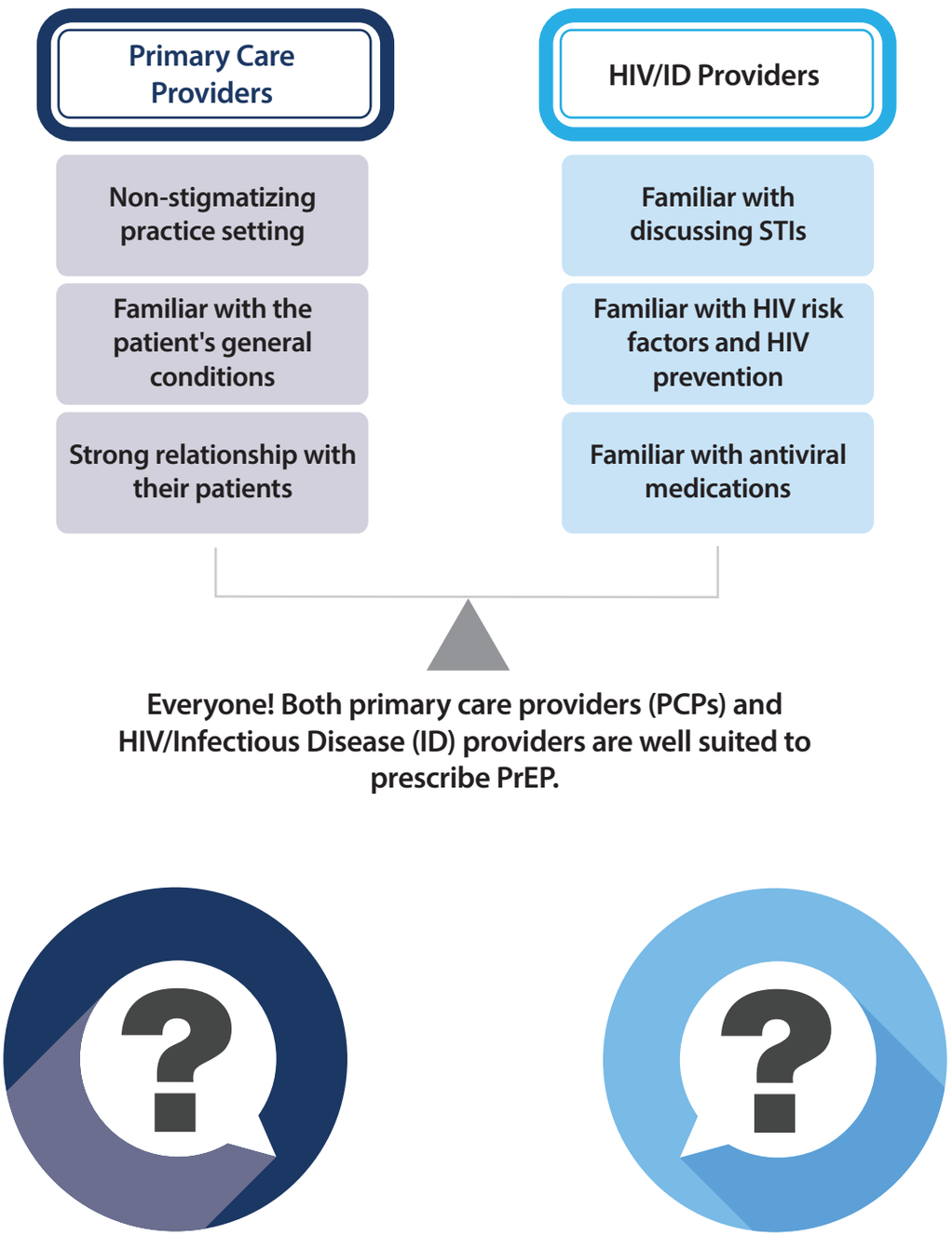


What Can Primary Care Providers do to Decrease HIV Infections?

In addition to counseling on risk reduction strategies, promoting and/or prescribing PrEP can reduce HIV infections.

- Why primary care providers?
- Do other providers have more knowledge about HIV management and sexual health?

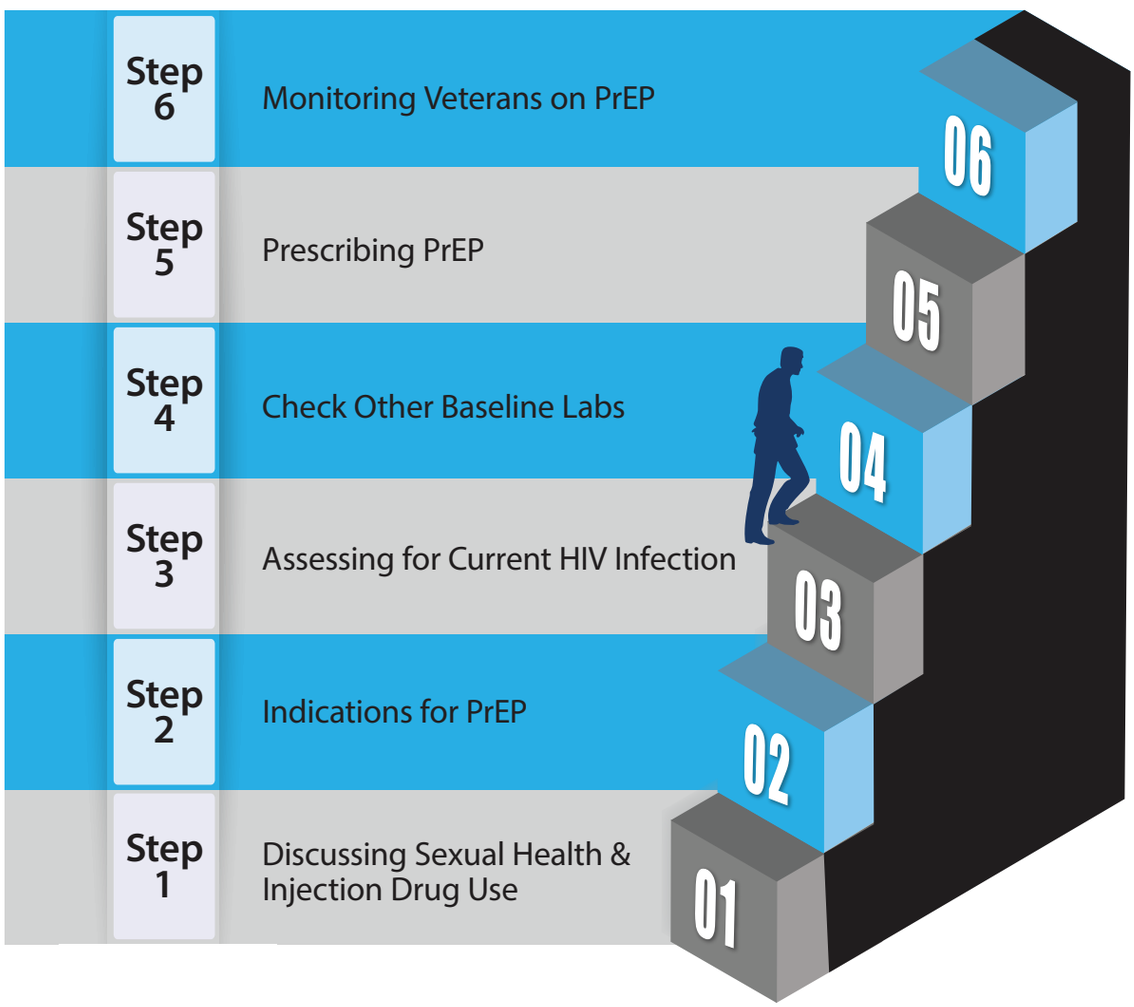
Figure 6. Who Should Prescribe PrEP?



Prescribing PrEP is Straightforward

When evaluating patients for PrEP, follow a step-wise approach to evaluate the risk of HIV infection and determine if PrEP is indicated. **HIV testing is essential since PrEP should only be used in patients who are HIV negative**. Counseling on methods to reduce HIV transmission and emphasizing the important of medication adherence with PrEP are very important to provide the greatest efficacy of the treatment.

Figure 7. Step-wise Approach to Prescribing PrEP



Step 1

Discussing Sexual Health & Injection Drug Use

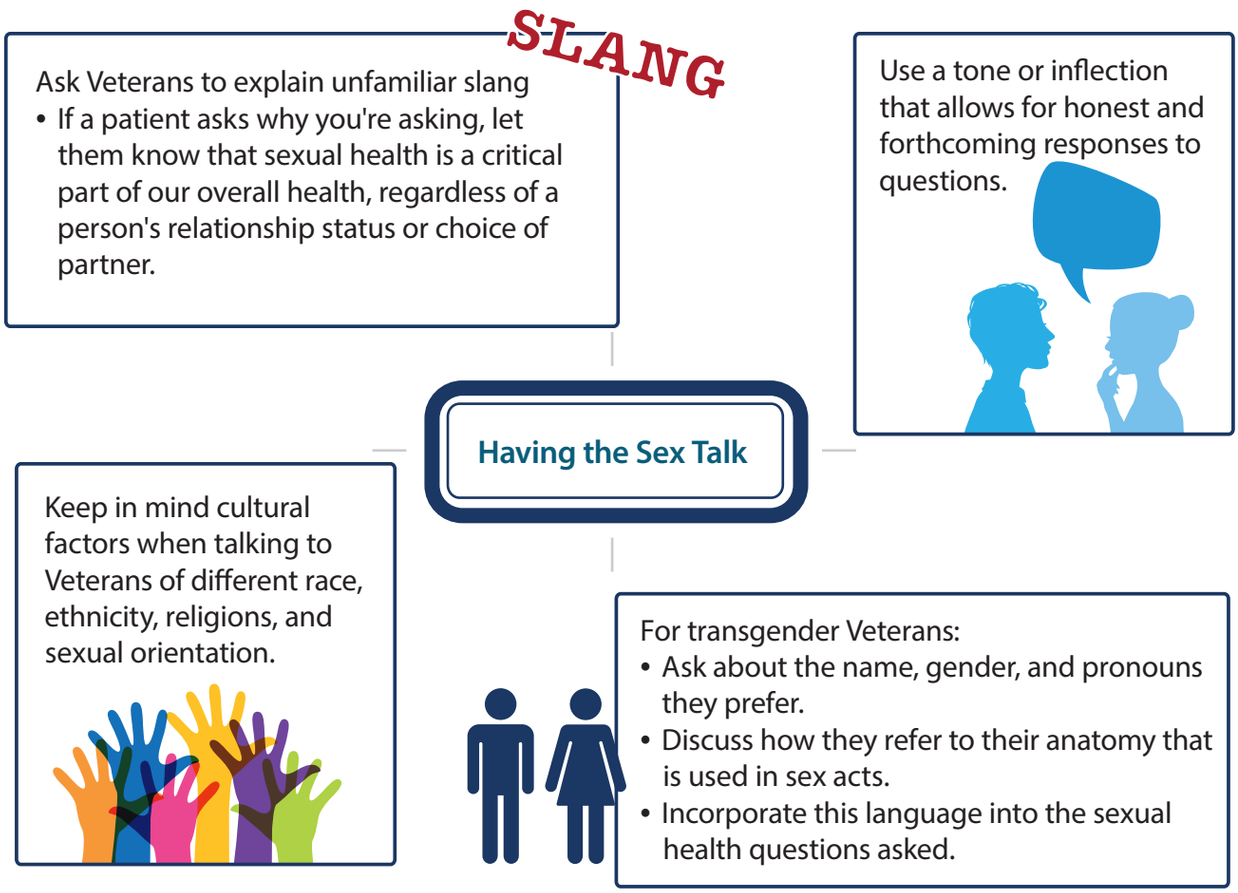
A Veteran's risk for HIV requires understanding of their social behaviors involving sex and drugs. Although a detailed history is useful, it is not necessary in determining if risk of HIV infection is at stake. For example, recent unprotected anal intercourse between MSM with unknown HIV status is sufficient risk to recommend PrEP regardless of other past or current behaviors.

Let's Talk About Sex

Figure 8. Questions About Sex Should:[11]

C O M M U N I C A T I O N

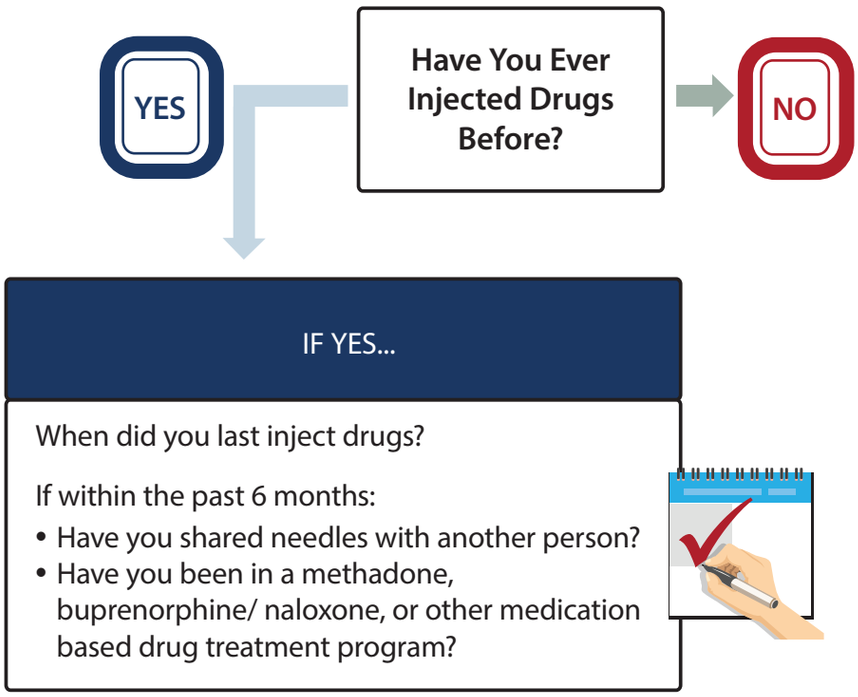
Figure 9. Pearls for Talking About Sex



For some Veterans, understanding the reasons for sex acts identifies those at increased risk of HIV and sexually transmitted infections (STIs).

Figure 10. Talking About Injection Drug Use

The National Institute on Drug Abuse (NIDA) has a comprehensive screening tool for primary care[12]. A quick screening question can be used to ask about illicit drug use.



Step 2

Indications for PrEP

Assess behaviors within the past 6 months and discuss PrEP with Veterans who meet any of these risks.

Table 2. CDC Recommended Indications for PrEP[6]

Population	Applies to	PrEP Indicated if Any is True
Sex or IDU with HIV Infected People	Any type of sexual activity or IDU with shared equipment	PrEP indicated in all Veterans in this category

Population	Applies to	PrEP Indicated if Any is True
Men who Have Sex with Men (MSM)	Any male sex partners in past 6 months (if also has sex with women, see Box below) Not in a monogamous partnership with a recently tested, HIV-negative man	Any anal sex without condoms in the past 6 months Any STI diagnosed or reported in the past 6 months Is in an ongoing sexual relationship with an HIV-positive partner
Heterosexually Active Men and Women	Any sex with opposite sex partners in past 6 months Not in a monogamous partnership with a recently tested, HIV-negative partner	A man who has sex with both women and men (behaviorally bisexual). If yes, evaluate MSM criteria above 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 (IDU or bisexual male partner) Is in an ongoing sexual relationship with an HIV-positive partner
IDU	Any injection of drugs in the past 6 months	Any sharing of injection or drug preparation equipment in the past 6 months Participant in a medication assisted treatment/ OUD clinic (methadone or buprenorphine/ naloxone) in the past 6 months Risk of sexual acquisition (see above categories)
Contraindications for PrEP • HIV positive or unknown HIV status • Creatinine clearance (CrCl) <60 mL/min • Prior severe reaction to TDF/FTC		

Veterans who have sex or share injection equipment with HIV infected people should be offered PrEP.

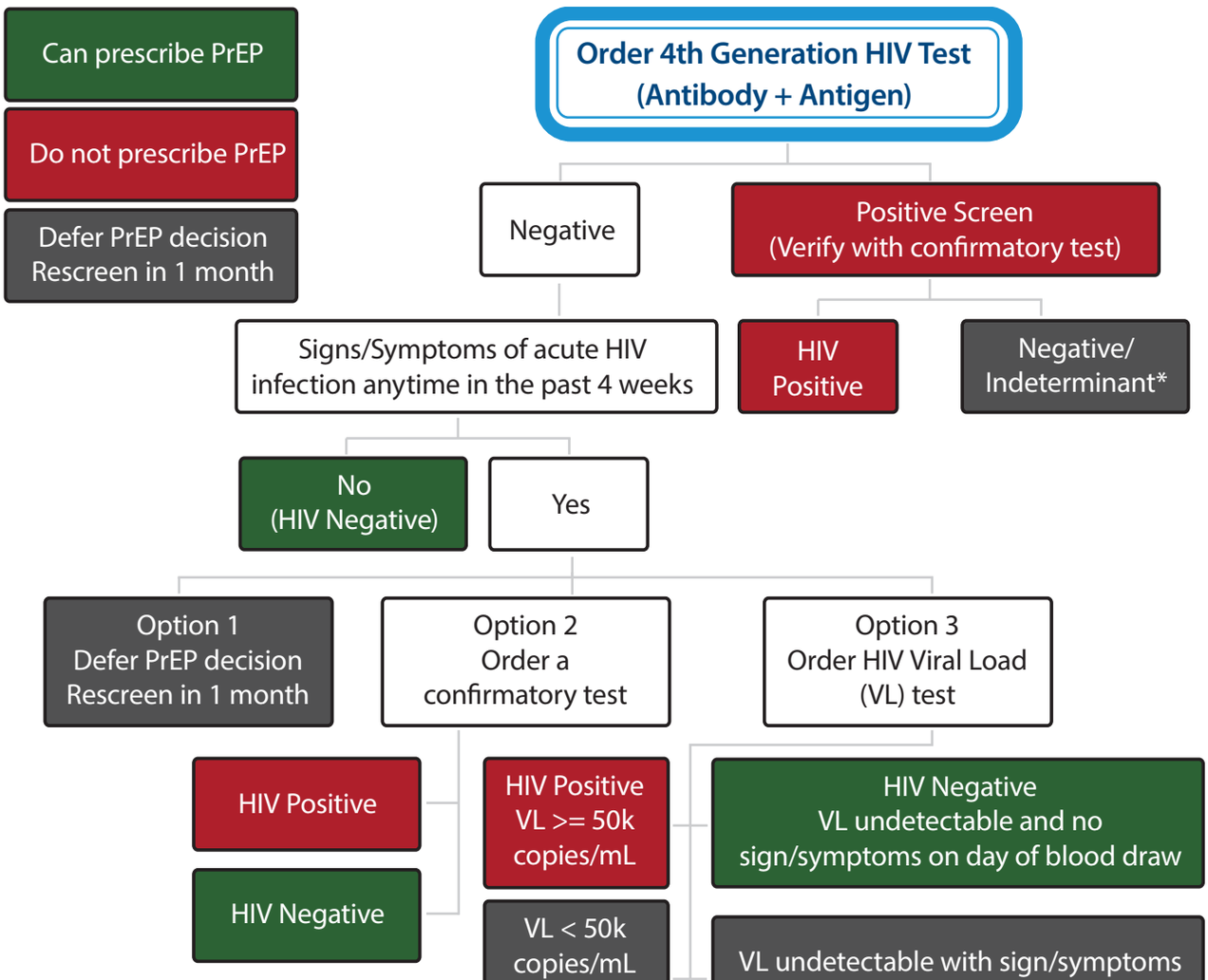
Step 3

Assessing for Current HIV Infection

Testing for HIV

Prior to starting PrEP, all patients must be tested for HIV and assessed for signs and symptoms of acute HIV infection. **HIV testing should be completed within 1 week prior to PrEP initiation.**[6] Refer HIV positive patients to an Infectious Disease Specialist. Use 4th generation assays, which test for both HIV antibodies and antigens, whenever possible, as this will detect HIV infections earlier (14 days vs 21 days or longer from exposure)[13]. All positive screens require a confirmatory test.

Figure 11. CDC's HIV Determination Algorithm[6]

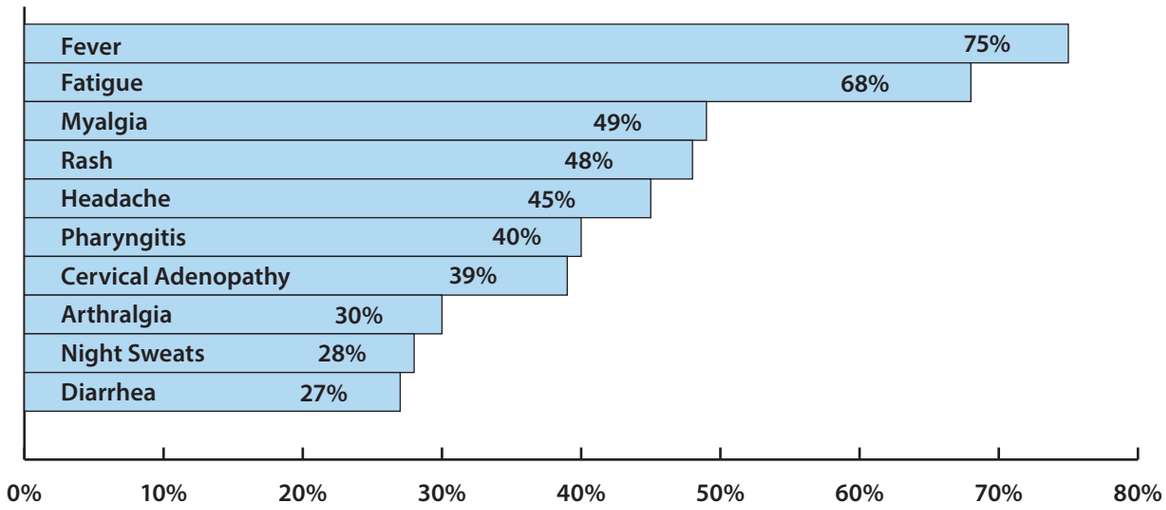


*Indeterminate results may occur during seroconversion and are commonly associated with a positive screen and negative or unknown confirmatory test. Defer PrEP decision until rescreened.

Assessment of Signs and Symptoms of HIV

All patients should be evaluated for signs and symptoms of acute HIV occurring within the past 4 weeks: If signs or symptoms of HIV infection are present, defer PrEP and retest for HIV in one month.

Figure 12. Frequency of Sign/Symptom During Acute HIV Infection[6]



PrEP should not be started in anyone with signs/symptoms of acute HIV.

Step 4

Check Other Baseline Laboratory Tests

The following tests should be performed prior to PrEP initiation to ensure treatment with PrEP is appropriate:

Table 3. Check Other Baseline Laboratory Tests[6]

Status	Laboratory Tests	General Information
Renal Function	Serum Creatinine	TDF/FTC is renally excreted and should be not used if creatinine clearance (CrCl) <60 mL/min
Sexually Transmitted Infections (STIs)	Syphilis (RPR or FTA) Gonorrhea* Chlamydia*	Swab samples should be obtained from all anatomically exposed sites (e.g., genital, rectal, pharyngeal) If positive, treat the STI or refer for treatment Both PrEP and STIs can be treated at the same time
Hepatitis B Virus (HBV)	Hepatitis B surface antibody (Anti-HBs) Hepatitis B surface antigen (HBsAg) Hepatitis B core antibody (Anti-HBc)	If unvaccinated (Anti-HBs is negative), initiate HBV vaccination** series If HBsAg is positive (suggestive of chronic HBV infection): • Check HBV viral load • Refer for hepatitis B evaluation • Advise of risk of HBV reactivation if PrEP is stopped
Hepatitis C Virus (HCV)	Hepatitis C Virus Antibody (HCV Ab)	Screening is recommended prior to starting PrEP If the HCV Ab screen is positive, check HCV RNA viral load If the HCV RNA is detectable, refer for evaluation of chronic HCV infection and possible treatment
Pregnancy	Urine beta-HCG (Pregnancy test)	PrEP can be safe in women who are pregnant or trying to conceive Determine pregnancy status and discuss the risks and benefits If attempting to conceive or pregnant with an HIV (+) spouse, refer to ID/fertility specialist for additional support

*Nucleic Acid Amplification Tests (NAAT) should be utilized if available.
**Consider additional screenings and vaccinations for MSM: Hepatitis A Vaccine, Human papilloma vaccine (Gardasil) for Veterans under 26 years old. FTA = fluorescent treponemal antibody; RPR = rapid plasma reagin; Urine Beta-HCG = urine beta-human chorionic gonadotropin.

Step 5

Prescribing PrEP

When prescribing PrEP, ensure that baseline laboratory testing is performed. If PrEP is indicated, prescribe initially as a 30 day supply. If the Veteran is tolerating it well, then subsequent prescriptions can be issued for up to a 90 day supply.

Figure 13. How to Prescribe PrEP and Baseline Laboratory Tests

- ✓ HIV Negative
- ✓ CrCl >= 60 mL/min
- ✓ Screened for:
  - HBV
  - HCV
  - Pregnancy
  - STIs (Syphilis, G/C)

FOR _____ DATE _____

Rx ADDRESS _____

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

Refills: 0

DR. _____ DR. _____
SUBSTITUTION PREMITTED DISPENSE AS WRITTEN

DEA NO. _____

Table 4. Key Discussion Points[6]

Discussion Points	
Adherence & Effectiveness	PrEP is most effective when taken every day – not just after sex PrEP is highly effective (>90%) when combined with other ways to reduce the risk of HIV transmission like using condoms or avoiding risky sexual behavior and using clean needle exchanges or receiving opioid use disorder (OUD) treatment. PrEP does not lower the risk of other STIs (e.g., syphilis, gonorrhea, herpes, or chlamydia). PrEP is continued while the patient is engaging in behaviors that put them at a high risk for acquiring HIV. When those risk factors change, the patient should be re-evaluated to determine if PrEP is still needed.

Discussion Points	
Side Effects	Side effects are minimal and TDF/FTC is generally well tolerated • Headache and nausea may occur but lessen within the first few weeks • Bone loss (1–3%) and reduced kidney function (3–5%) can occur with treatment but usually improve when PrEP is stopped
Other	• Veterans with hepatitis B, who are started on PrEP, should not stop the medication suddenly as rebound hepatitis may occur • PrEP can be administered while trying to conceive and during pregnancy. HIV-uninfected persons trying to conceive with an HIV-infected partner should be referred to an ID or fertility specialist for counseling on strategies for preventing HIV transmissions, including PrEP • Since the VA is not able to provide care for non-Veterans, refer partners of patients to community providers who provide PrEP • **https://preplocator.org/**
General Risk Reduction Strategies	• Discuss behaviors to reduce risk of HIV infection, such as knowing the HIV status of a partner and using barrier methods for protection • For IDUs, discuss knowing the HIV status of injecting partners, utilizing clean needles or needle exchanges and engaging in treatment for addiction • Refer Veterans with substance use or mental health disorders to appropriate treatment

Ensure Veterans understand the importance of adherence with PrEP. Protection against HIV infection with PrEP is directly correlated with adherence.

Step 6

Monitoring Patients on PrEP

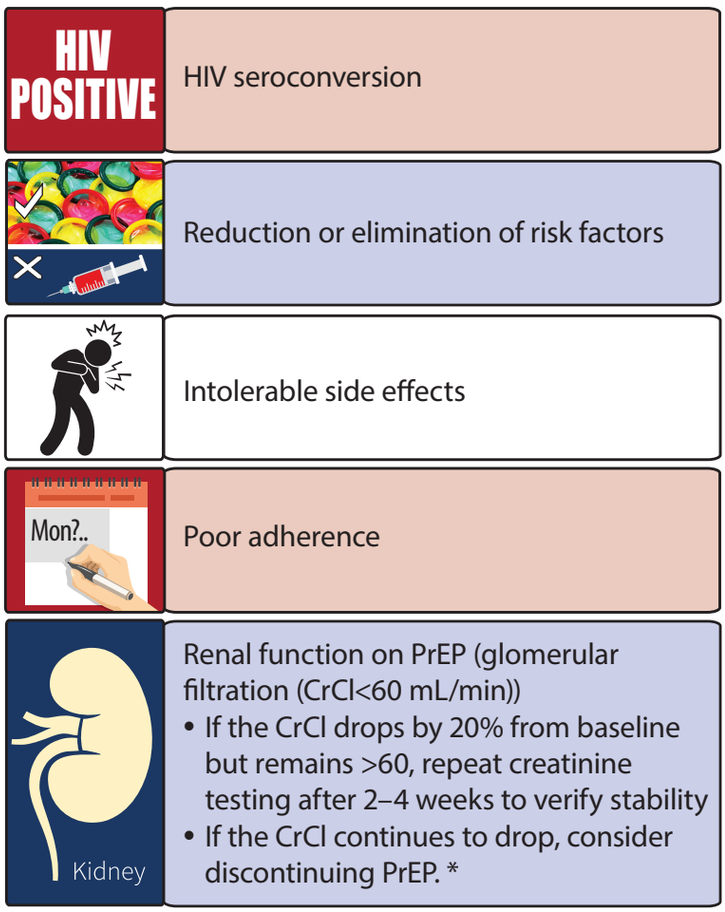
Veterans who are prescribed PrEP should be evaluated for comorbidities like substance use disorder (SUD) and medication adherence with PrEP should be discussed at every visit. Laboratory testing, including HIV testing, should be monitored to ensure that using PrEP is still indicated.

Table 5. Frequency of Monitoring Patients on PrEP[6]

Category	Screen/Test	General Information
Every Visit		
Mental Health	Substance Use Disorder	Refer to as necessary or consider managing in Primary Care if Veteran prefers
General Counseling	N/A	Provide risk reduction counseling
Medication Adherence	N/A	Ask the patient about adherence • How does the Veteran remind him/herself Review fill history
Monitor Every 3 Months		
HIV Status	HIV test Acute HIV signs/symptoms	Use a 4th Generation test – See **page 12** Signs and symptoms – See **page 13**
Pregnancy	Urine beta-HCG	
Monitor Every 6 Months		
STIs	Syphilis Gonorrhea* Chlamydia*	RPR or FTA Swab samples should be obtained from all anatomically exposed sites (e.g., genital, rectal, pharyngeal)
Renal Function	Serum Creatinine	Consider more frequently in patients with additional risks: • Chronic kidney disease • Hypertension • Diabetes • Age >50
Monitor Every 1 Year		
Reassessment	N/A	Re-evaluate the need for PrEP
Hepatitis C Status	HCV Antibody (Ab)	For those injecting drugs
Note: Long term use of PrEP (TDF/FTC) should include osteoporosis screenings every 2–3 years		

*Nucleic Acid Amplification Tests (NAAT) should be utilized. FTA = fluorescent treponemal antibody; RPR = rapid plasma reagin; Urine Beta-HCG = urine beta-human chorionic gonadotropin.

Figure 14. Stopping PrEP? When Should This Be Considered?[6]



*Decisions to discontinue PrEP should balance the Veteran's risk for HIV infection versus risk for further deterioration in renal function. CrCl = creatinine clearance.

Veterans should be advised not to stop taking PrEP without speaking to their provider, especially if they have hepatitis B as clinically significant rebound hepatitis may occur.

VA guidance recommends continuing PrEP for 28 days beyond the last risky exposure.[14]

When PrEP is discontinued, document:

- Veteran's HIV status
- Reason for discontinuation
- Recent adherence
- Recent risk behaviors

If a Veteran becomes HIV positive while taking PrEP, stop PrEP immediately and refer urgently for HIV care.

Talking to Veterans About Positive HIV Test Results

Delivering the result of an HIV test can be a critical interaction between a Veteran and health care provider. Results should be discussed in person (and within 7 days – for results requiring action – and 14 days for all others as described in the **VHA Directive 1088 Communicating Test Results to Providers and Patients**) and the discussion should help them understand the significance of the result. Patients should be referred for medical follow up and other appropriate services. In the event that the patient is too overwhelmed with the test results to process additional information, make a second visit to go over referral and other resources.

Table 6. Framing the Conversation Around HIV Test Results

Step	Key Considerations
1. Greet the patient and frame the discussion.	✓ Example: *"You are here for your HIV test results. Are you ready for those or is there anything you'd like to discuss first?"*
2. Deliver the HIV test result with a very brief interpretation.	✓ Use simple, direct language and a neutral tone ✓ Example: *"your test result is (negative/positive). This means…"*
3. Pause to allow the patient time to react.	✓ Do not assume you know what the result means to the patient; do not make value comments about it ✓ If the result is positive, patients often do not hear anything after the result is delivered. Give time for the patient to absorb the information

Step	Key Considerations
4. Provide support, education, and counseling according to what the patient needs and accepts.	✓ Patients' reactions may be strong and emotional ✓ It may take time for the patient to process new information and be ready for questions, additional information, or referrals ✓ Schedule another session for information and counseling if patients are unable to hear anything beyond the test result ✓ Support and counseling may include: emotional support, support around stigma, information about notification and protection of partners, recommendations for preventing HIV transmission to others, and accurate information about HIV and its medical management ✓ If patients have a history of psychiatric illness or substance use, notify their mental health providers in advance so they can be present or available during the session ✓ For patients with depression or a history of depression, be sure to assess for suicidal ideation and connect them to services appropriately
5. Summarize the discussion.	✓ Provide a brief summary of what you discussed and next steps
6. Give referrals, as appropriate, in writing.	✓ If negative: • Assess for risk factors (see pages **pages 10–11**) • Refer for prevention resources and give recommendations about future HIV testing ✓ For HIV-positive patients: **LINK THEM TO MEDICAL CARE**. Ideally, provide the newly diagnosed patient with an appointment to be seen in a VA or community clinic within 1–2 weeks. If you have questions about who best to refer patients to, contact your Infectious Disease Service prior to seeing the patient ✓ Provide any referrals to mental health services and other services as appropriate
7. Document the HIV result in the patient's chart.	✓ Include a summary of the education and counseling given to the patient, the patient's mental status, and referrals made

What About Intermittent Use of PrEP?

The CDC recommends only continuous daily use of oral PrEP with TDF/FTC.[6] PrEP used less frequently may not yield the same results.

What About Drug Resistance?

Little evidence supports drug resistance as a significant problem in either clinical trials or real-world prescribing of PrEP.[6,15] However, even an adherent person can become infected with a HIV strain resistant to PrEP. One such case has been reported.[16]

A Note about Non-Occupational Post-Exposure Prophylaxis (nPEP): nPEP ≠ PrEP

Non-occupational post-exposure prophylaxis (nPEP) prevents HIV infection after a known or suspected HIV exposure and is started within 72 hours of the event (e.g., unprotected sex with someone who is HIV positive). nPEP involves a regimen of three antiretroviral agents used for the treatment of HIV over a limited period of time, such as 28 days – recommended by CDC and Department of Health and Human Services (DHHS).[17] Discuss PrEP with all Veterans who have completed nPEP.

Summary

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

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Notes

Notes

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 Service 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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