November 8, 2016

Dear Colleague,

As of 2013, over 22,000 residents of the Greater Houston Area are known to be living with HIV. Despite advances in HIV testing 1,200 Houstonians are diagnosed with HIV every year.

Pre-Exposure Prophylaxis (PrEP) is a powerful prevention tool against HIV transmission. PrEP is a way for people who do not have HIV to stay HIV-negative by taking a daily pill. Yet, one in three primary care doctors and nurses are not aware PrEP exists. The Centers for Disease Control and Prevention (CDC) recommends PrEP for HIV-negative individuals who are at substantial risk for contracting HIV. When taken consistently once a day as prescribed, PrEP reduces the risk of HIV infection from sex by more than 90%, and can be combined with condoms and other prevention methods to provide even more protection.

The National HIV/AIDS Strategy: Updated to 2020 supports full access to comprehensive PrEP services for those whom it is appropriate and desired, including support for medication adherence for those using PrEP. In aligning with the National HIV/AIDS Strategy, the Houston Health Department (HHD) urges clinical providers and prevention programs to use PrEP as a first-line intervention for individuals who could most benefit, including gay men and other men who have sex with men, transgender persons, persons who inject drugs, as well as men and women at high risk for infection.

HHD invites you to consider prescribing PrEP to help us turn the tide of the HIV epidemic in Houston. Included in this PrEP provider toolkit are resources to support integrating PrEP in your practice. The resources are structured around the following primary HIV prevention practices:

1. How to screen for PrEP, to ensure patient meets requirements for use of PrEP
2. How to Prescribe PrEP, detailed steps of process utilized for prescribing medication
3. How to follow up with patients to ensure PrEP is working for them.
4. How to bill for PrEP services and get reimbursed from insurance companies and Medicare.
In addition to the PrEP provider toolkit, the HHD will offer training and information sessions. HHD is creating a PrEP Provider Directory for the Greater Houston Area who is prescribing PrEP. If you wish to learn more educational opportunities and/or to register your practice as part of the provider directory, please contact Jovaun P. Hicks, PrEP Outreach Specialist. He can be reached by email prep@houstontx.gov or 832-393-4555.

You play a pivotal role in fighting HIV in our community. Please join the HHD in our efforts to ensure Houstonians are aware of and have access to this important HIV prevention intervention.

Sincerely,

Marlene L. McNeese
Bureau Chief
Bureau of HIV/STD and Viral Hepatitis Prevention
PrEP Provider Toolkit

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Talking to patients about their sexual health is often postponed due to urgent care issues, provider discomfort, or anticipated patient discomfort. However, routinely taking a sexual history is important for identifying patients at risk of acquiring HIV and other STIs. Use the SAFE discussion method to help guide your conversations about sexual health:

**S**tart the sexual history conversation by stating that it is routine practice. Explain how information about your patients’ sexual history will be confidential, and will enable you to provide appropriate sexual healthcare.

**A**ssess your patients’ risk for acquiring STIs, including HIV. Though some patients may be at greater risk than others, it’s important to have this discussion with all of your patients.

**F**ind out about your patients’ sexual history in the past 6 months and current practices through a series of questions:

- **Have you had sex with men, women, or both?**
  - “How many men and/or women have you had sex with?”

  **For men who have sex with men (MSM):**
  - “Do you have insertive sex (you are the top), receptive sex (you are the bottom), or both?”
  - “How many times did you have anal sex without a condom?”
  - “Have you used methamphetamine [such as crystal or speed]?”
  - “How many of your sex partners did not know their status or were HIV positive?”
    - “With these HIV-positive male partners, how many times did you have anal sex without a condom?”

  **For heterosexual men and women:**
  - “How many times did you have vaginal or anal sex when you (if a male patient) or your partner (if a female patient) did not use a condom?”
  - “How many of your sex partners did not know their status or were HIV positive?”
    - “With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?”

- **Have you had sex under the influence of alcohol and/or recreational drugs?**
- **Have you been screened for HIV, STIs, and/or hepatitis B and C? If so, what were the results?**
- **Are you up to date on your hepatitis A and B and/or HPV vaccinations?**

**D**ucate your patients on the importance of condoms, as well as other components of a comprehensive HIV prevention approach, including routine HIV and STI testing, and sexual history conversations. For HIV-positive patients, initiating and adhering to treatment helps prevent HIV transmission to negative partners. For HIV-negative patients at risk of HIV infection, consider additional prevention methods such as behavioral counseling, PrEP (pre-exposure prophylaxis), and PEP (post-exposure prophylaxis).

Using the SAFE discussion method can help you gain a better understanding of your patients’ risk status and sexual behaviors. By guiding your patients toward safer encounters that may reduce their risk of contracting or transmitting HIV, you can help end the epidemic.

HPV=human papillomavirus; STI=sexually transmitted infection.

*Anal sex is the riskiest type of sex for contracting or transmitting HIV. Receptive anal sex (‘bottoming’) results in a higher risk of HIV infection than insertive anal sex (‘topping’).*
You can help protect your patients at risk of HIV infection by utilizing a comprehensive approach. Be proactive.

Combine routine HIV and STI testing with sexual history conversations and education on the importance of condoms.¹ ³

- For HIV-positive patients, initiating and adhering to treatment helps prevent HIV transmission to negative partners.
- For HIV-negative patients at risk of HIV infection, consider additional prevention methods such as behavioral counseling, PrEP (pre-exposure prophylaxis), and PEP (post-exposure prophylaxis).

For more information, visit PreventHIV.com

Preexposure prophylaxis (PrEP) is a medicine taken daily that can be used to prevent getting HIV. PrEP is for people without HIV who are at very high risk for getting it from sex or injection drug use. People at high risk who should be offered PrEP include about 1 in 4 sexually active gay and bisexual men*, 1 in 5 people who inject drugs, and 1 in 200 sexually active heterosexual adults. When taken every day, PrEP is safe and highly effective in preventing HIV infection. PrEP is even more effective if it is combined with other ways to prevent new HIV infections like condom use, drug abuse treatment, and treatment for people living with HIV to reduce the chance of passing the virus to others. Many people who can benefit from PrEP aren’t taking it. If more health care providers know about and prescribe PrEP, more HIV infections could be prevented.

Health care providers can:

- Test patients for HIV as a regular part of medical care. Discuss HIV risks and continued use of prevention methods, including condom use, with all patients.
- Follow the 2014 PrEP Clinical Practice Guidelines to perform recommended tests and prescribe PrEP to patients without HIV who could benefit.
- Counsel patients who can benefit from PrEP on how to take it every day and help them apply for insurance or other programs to pay for PrEP.
- Schedule appointments for patients using PrEP every 3 months for follow-up, including HIV testing and prescription refills.

*This fact sheet refers to all men who have sex with men (MSM) as gay or bisexual. Sexually active refers to people who have had sex in the past year.

Want to learn more? www.cdc.gov/vitalsigns/HIVPrEP
PrEP is for some people at very high risk for getting HIV:

- 1 in 4 sexually active gay and bisexual adult men without HIV who:
  - Have an HIV-positive partner, or
  - Have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown and
    - Have anal sex without a condom, or
    - Recently had a sexually transmitted infection (e.g. syphilis).

- 1 in 5 adults without HIV who inject drugs who:
  - Share needles or equipment to inject drugs, or
  - Recently went to a drug treatment program (specifically, a methadone, buprenorphine, or suboxone treatment program), or
  - Are at risk for getting HIV from sex.

- 1 in 200 sexually active heterosexual adults without HIV who:
  - Have an HIV-positive partner, or
  - Have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown and
    - Do not always use a condom for sex with people who inject drugs, or
    - Are women who do not always use a condom for sex with bisexual men.

Not enough health care providers know about PrEP.

- In 2015, 34% of primary care doctors and nurses had never heard of PrEP (2015 survey).

- All prescribing health care providers can deliver PrEP care, including test for HIV, ask about sex and drug use behaviors to determine their patient’s risk of getting HIV, and prescribe PrEP when indicated.

Problem:

Many people at very high risk for HIV infection are not getting PrEP.

Increasing PrEP Use

A focused effort by New York State to increase PrEP uptake started in June 2014 and included:

1. Provider Training
2. Raising Awareness
3. Ensuring Medicaid Coverage

40,000
About 40,000 HIV infections are diagnosed each year in the US.

SOURCE: NYS Medicaid Data Warehouse (based on Medicaid data loaded through July 2015).
Any prescribing health care provider can deliver PrEP care.

1. **Test** for HIV including acute infection.
   - If HIV negative, ask about sex and drug use behaviors.
   - If HIV positive, provide or refer patient for HIV treatment and other services to maintain health and prevent further spread of HIV.

2. **Order** recommended tests if patient is interested in PrEP and could benefit from it.
   - If tests show reason not to prescribe PrEP (e.g. abnormal kidney function), discuss other prevention methods.

3. **Help** patient apply for insurance or other programs to pay for PrEP.
   - Most public and private insurance programs cover PrEP, and patients can get help with their co-payments.

4. **Prescribe** PrEP and instruct patient to take one pill every day.
   - Currently Truvada® is the only medicine approved by the FDA for PrEP.

5. **Follow-up** Schedule appointments every 3 months for follow-up, including HIV testing and prescription refills.

**Have questions?**


Call the PrEP Clinician Helpline: (855) 448-7737 or (855) HIV-PrEP

**SOURCE:** 2014 PrEP Clinical Practice Guidelines.
What Can Be Done?

The Federal government is

- Ensuring coverage of recommended preventive services, such as HIV testing, without cost sharing in most health insurance plans.
- Educating health care providers and people at high risk about PrEP through health department programs, social marketing campaigns, and other training and technical assistance efforts.
- Helping to monitor PrEP use and its effects.

Health care providers can

- Test patients for HIV as a regular part of medical care. Discuss HIV risks and continued use of prevention methods, including condom use, with all patients.
- Follow the 2014 PrEP Clinical Practice Guidelines to perform recommended tests and prescribe PrEP to patients without HIV who could benefit.
- Counsel patients who can benefit from PrEP on how to take it every day and help them apply for insurance or other programs to pay for PrEP.
- Schedule appointments for patients using PrEP every 3 months for follow-up, including HIV testing and prescription refills.

Everyone can

- Get tested for HIV and know their status.
- Learn how HIV is transmitted and how it can be prevented.
- Talk to their health care providers about HIV risk and ways to prevent it, including PrEP, condom use, abstinence, drug treatment, and HIV treatment for people with HIV.

Everyone taking PrEP can

- Take PrEP every day to give it the best chance to work.
- See their health care provider every 3 months for follow-up, including HIV testing and PrEP refills.
- Take other actions to further reduce HIV and STD risk. [www.cdc.gov/hiv/basics/prevention.html](http://www.cdc.gov/hiv/basics/prevention.html)

State and local health departments and community-based organizations can

- Raise awareness about PrEP use, train health care providers, and develop policies and procedures that will increase access to PrEP.

Monitor PrEP use among those at highest risk for HIV.

Educate people about risky sexual and drug use behaviors and ways to reduce their risk, including PrEP and how to get it.

For more information, please contact
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348
[www.cdc.gov](http://www.cdc.gov)
Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Publication date: 11/24/2015
IMPORTANT DRUG WARNING

Subject: FDA-Required Risk Evaluation Mitigation Strategy (REMS) for TRUVADA® [TRUVADA for a pre-exposure prophylaxis (PrEP) indication]

A negative HIV-1 test must be confirmed immediately before starting TRUVADA for a PrEP indication and reconfirmed during treatment. Drug-resistant HIV-1 variants have been identified with the use of TRUVADA for a PrEP indication following undetected HIV-1 infection.

Dear Healthcare Provider:

Gilead Sciences, Inc., would like to inform you of the FDA-approved REMS for TRUVADA (a fixed-dose combination of emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg) for a PrEP indication in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. TRUVADA for a PrEP indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.

The FDA has determined that a REMS is necessary to ensure that the benefits of TRUVADA for a PrEP indication outweigh its risks.

The goals of the REMS for TRUVADA for a PrEP indication are to inform and educate prescribers and uninfected individuals at high risk for acquiring HIV-1 infection about:

- The importance of strict adherence to the recommended dosing regimen
- The importance of regular monitoring of HIV-1 serostatus to avoid continuing to take TRUVADA for a PrEP indication, if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants
- The fact that TRUVADA for a PrEP indication must be considered as only a part of a comprehensive prevention strategy in order to reduce the risk of HIV-1 infection and that other preventive measures should also be used.

Before initiating TRUVADA for a PrEP indication

You MUST confirm a negative HIV-1 status immediately before prescribing TRUVADA for a PrEP indication in an uninfected individual. Drug-resistant HIV-1 variants have
been identified with use of TRUVADA for a PrEP indication following undetected HIV-1 infection.

Do NOT prescribe TRUVADA for a PrEP indication to patients with HIV-1 infection or to individuals with signs or symptoms consistent with acute HIV-1 infection, such as fever, headache, fatigue, arthralgia, vomiting, myalgia, diarrhea, pharyngitis, rash, night sweats, and adenopathy (cervical and inguinal).

**Prescriber Action**

You should review and discuss the content of the Agreement Form for Initiating TRUVADA for Pre-exposure Prophylaxis with an HIV-negative person considering or taking TRUVADA for a PrEP indication and refer to the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP) regarding the management of an uninfected individual taking TRUVADA for a PrEP indication. (Access Agreement Form and Checklist via www.TRUVADApreprems.com)

The most important information you should know about prescribing TRUVADA for a PrEP indication to reduce the risk of acquiring HIV-1 infection is:

- TRUVADA for a PrEP indication should only be used as part of a comprehensive prevention strategy including consistent and correct use of condoms and risk reduction counseling

- All uninfected individuals at high risk for acquiring HIV-1 infection should only take TRUVADA for a PrEP indication after HIV-1 negative status is confirmed, to reduce the risk of development of resistant HIV-1 variants

- All uninfected individuals at high risk must strictly adhere to the recommended TRUVADA for a PrEP indication daily oral regimen

**Management of Uninfected Individuals**

Uninfected individuals at high risk should:

- Be counseled about safer sex practices, including consistent and correct use of condoms, knowledge of their HIV-1 status and that of their partner(s), and regular testing for other sexually transmitted infections that can facilitate HIV-1 transmission

- Be tested to confirm that they are HIV-1 negative immediately before starting TRUVADA for a PrEP indication

- Be tested for acute HIV-1 infection and checked for any signs or symptoms consistent with acute HIV-1 infection, such as fever, headache, fatigue, arthralgia,
vomiting, myalgia, diarrhea, pharyngitis, rash, night sweats, and adenopathy (cervical and inguinal)

- Be screened at least every 3 months for HIV-1 status as determined by their prescriber to reconfirm that they are HIV-1-negative while taking TRUVADA for a PrEP indication to reduce the risk of acquiring HIV-1 infection.

- Have their creatinine clearance (CrCl) estimated prior to initiating and as clinically appropriate during therapy with TRUVADA. Do NOT use TRUVADA for a PrEP indication if the estimated CrCl is $<60$ mL/min. In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of TRUVADA, and periodically during TRUVADA therapy. If a decrease in estimated CrCl is observed in uninfected individuals while using TRUVADA for a PrEP indication, the prescriber should evaluate potential causes and reassess potential risks and benefits of continued use.

- Be tested for the presence of hepatitis B virus (HBV) before starting on TRUVADA for a PrEP indication. Severe acute exacerbations of hepatitis B have been reported in individuals who are co-infected with HBV and HIV-1 and have discontinued TRUVADA. Uninfected individuals taking TRUVADA for a PrEP indication who are infected with HBV need close medical follow-up for several months to monitor for exacerbations of hepatitis B in the event TRUVADA is discontinued. HBV-uninfected individuals should be offered vaccination as appropriate.

- Be informed that TRUVADA has only been evaluated in a limited number of women during pregnancy and postpartum. Available human and animal data suggest that TRUVADA does not increase the risk of major birth defects overall compared to the background rate. There are, however, no adequate and well-controlled trials in pregnant women. Because the studies in humans cannot rule out the possibility of harm, TRUVADA should be used during pregnancy only if clearly needed. If an uninfected individual becomes pregnant while taking TRUVADA for a PrEP indication, careful consideration should be given to whether use of TRUVADA should be continued, taking into account the potential increased risk of HIV-1 infection during pregnancy.

**REMS Website** ([www.TRUVADApreprems.com](http://www.TRUVADApreprems.com))

The REMS website provides access to the following:

- Specific information regarding the risks of TRUVADA for a PrEP indication

- Training and educational materials for prescribers and uninfected individuals considering or taking TRUVADA for a PrEP indication, including the Agreement Form for Initiating TRUVADA for Pre-exposure Prophylaxis (PrEP) and
Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

- A mechanism to report completion of review of the training material
- A link to participate in the Knowledge, Attitude, and Behavior (KAB) REMS survey regarding important safety information associated with the use of TRUVADA for a PrEP indication

**Reporting Adverse Events**
To report any adverse events, suspected to be associated with the use of TRUVADA for a PrEP indication, contact:

- Gilead Sciences, Inc., at 1-800-445-3235 and/or
- FDA’s MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), or online (https://www.accessdata.fda.gov/scripts/medwatch/)

This letter is not intended as a comprehensive description of the risks associated with the use of TRUVADA for a PrEP indication. Please read the enclosed Prescribing Information, including the BOXED WARNING, and the Medication Guide for more information.

Sincerely,

William Guyer, PharmD
Senior Vice President, Medical Affairs
Checklist for Prescribers:  
Initiation of Truvada® for Pre-exposure Prophylaxis (PrEP)

Instructions: Complete checklist at each visit and file in individual’s medical record.

I have completed the following prior to prescribing TRUVADA for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking TRUVADA for a PrEP indication:

Lab Tests/Evaluation

☐ Completed high risk evaluation of uninfected individual
☐ Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication
  - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: TRUVADA for a PrEP indication is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive)
☐ Performed HBV screening test
☐ Confirmed estimated creatinine clearance (CrCl) >60 mL/min prior to initiation and periodically during treatment. In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of TRUVADA and periodically while TRUVADA is being used. If a decrease in estimated CrCl is observed in uninfected individuals while using TRUVADA for a PrEP indication, evaluate potential causes and reassess potential risks and benefits of continued use
☐ Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HBV medications
☐ Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

Counseling/Follow-up

☐ Discussed known safety risks with use of TRUVADA for a PrEP indication
☐ Counseled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening tests (at least every 3 months), while taking TRUVADA for a PrEP indication to reconfirm HIV-1-negative status
☐ Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
☐ Counseled on the importance of adherence to daily dosing schedule
☐ Counseled that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention strategy
☐ Educated on practicing safer sex consistently and using condoms correctly
☐ Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)
☐ Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
☐ Offered HBV vaccination as appropriate
☐ Provided education on where information about TRUVADA for a PrEP indication can be accessed
☐ Discussed potential adverse reactions
☐ Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk
TRUVADA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. The following factors may help to identify individuals at high risk:

- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and one or more of the following:
  - Inconsistent or no condom use
  - Diagnosis of sexually transmitted infections
  - Exchange of sex for commodities (such as money, shelter, food, or drugs)
  - Use of illicit drugs, alcohol dependence
  - Incarceration
  - Partner(s) of unknown HIV-1 status with any of the factors listed above
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<td>87537</td>
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<td>87810</td>
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<td>Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.</td>
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<td>Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.</td>
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# Medicaid Billing and Coding Guide for HIV Prevention

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<th>Fee Effective Date</th>
<th>Age</th>
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<td>Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.</td>
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<td>99214</td>
<td>Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.</td>
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<td>21-55 YEARS</td>
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<td>99215</td>
<td>Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.</td>
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<td>99401</td>
<td>Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes</td>
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<td>Approximately 35 minutes</td>
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<tr>
<td>99403</td>
<td>Approximately 45 minutes</td>
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<tr>
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<td>99204</td>
<td>Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.</td>
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<td>21-55 YEARS</td>
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<tr>
<td>99205</td>
<td>Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.</td>
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<td>TH</td>
<td>$22.14</td>
<td>9/1/2007</td>
<td>21-55 YEARS</td>
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8/3/2017
1. What is Truvada® as PrEP?
Truvada® as PrEP, or pre-exposure prophylaxis, is the use of antiretroviral medication to prevent the acquisition of the HIV infection. PrEP is used by HIV-negative people who are at risk of being exposed to HIV through sexual contact or injection drug use. Truvada® as PrEP is a pill taken once daily that contains two HIV medications: Tenofovir and Emtricitabine. The combination of these two drugs, when used for PrEP, is called Truvada®. Currently, Truvada® is the only antiretroviral medication approved by the FDA for use as PrEP.

2. How effective is Truvada® as PrEP?
When used consistently, Truvada® reduces the risk of contracting HIV from sex by more than 90%; and by 70% for injection drug users. Adherence to PrEP is essential; clinical trials have shown a positive correlation between adherence and PrEP efficacy.

3. Who can prescribe Truvada® as PrEP?
Any licensed provider can prescribe Truvada® as PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who see members of populations at high risk of HIV on a routine basis are encouraged to offer Truvada® as PrEP to all eligible and interested patients.

4. What are the clinical practice guidelines?
The Centers for Disease Control and Prevention (CDC) provides comprehensive guidelines, including a Clinical Providers Supplement, for prescribing Truvada® as PrEP. The Clinical Providers’ Supplement contains several tools for clinicians, such as billing codes, provider information sheets, patient/provider checklists, patient information sheets, a risk incidence assessment, and supplemental counseling information. For more information, visit www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

*For guidance documents from Gilead, please visit at www.truvadapreprems.com.

5. What side effects may be experienced by patients?
Some patients will experience serious side effects including loss of bone density (1 in 100) or renal issues (1 in 200). More common side effects include: upset stomach, headache, vomiting, and loss of appetite. These side effects will typically fade during the first month of taking Truvada®. However, if a patient experiences side effects that do not go away within a month, the patient should notify his/her provider immediately.

6. What happens if my patient tests positive while taking Truvada® as PrEP?
Truvada® should be discontinued immediately if: 1) the patient becomes HIV-infected; 2) the patient experiences toxicity or symptoms that cannot be managed; or 3) the patient becomes pregnant.
7. Who may benefit from Truvada® as PrEP?
Per CDC Guidelines and local epidemiology, Truvada® as PrEP may be appropriate for the following populations:

<table>
<thead>
<tr>
<th>Signs of Substantial HIV Risk</th>
<th>Men Who Have Sex With Men (MSM)</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
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<tbody>
<tr>
<td>- MSM of color (African American and Latino)</td>
<td>- HIV-positive sexual partner</td>
<td>- HIV-positive injecting partners</td>
<td></td>
</tr>
<tr>
<td>- HIV-positive sexual partner</td>
<td>- Recent bacterial STI</td>
<td>- Sharing injection equipment</td>
<td></td>
</tr>
<tr>
<td>- Recent bacterial STI</td>
<td>- High number of sex partners</td>
<td>- Recent drug treatment (but currently injecting)</td>
<td></td>
</tr>
<tr>
<td>- High number of sex partners</td>
<td>- History of inconsistent or no condom use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- History of inconsistent or no condom use</td>
<td>- Commercial sex work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Commercial sex work</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other groups/individuals at risk for HIV contraction who may benefit from PrEP:
1. Transgender individuals
2. Individuals engaging in high-risk sexual behaviors
3. Individuals who use stimulant drugs associated with high-risk behaviors, such as methamphetamine
4. Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) and demonstrate continued high-risk behavior or have used multiple courses of nPEP

Truvada® should not be prescribed to individuals who: 1) are HIV-positive; 2) display renal insufficiency; or 3) indicate they are not ready to adhere to a regimen of oral Truvada® taken once daily, in conjunction with provider visits every 3 – 4 months for lab work and HIV testing.

8. Is there financial assistance for patients to pay for Truvada® as PrEP?
For patients who have insurance:
- If patient has a high deductibles or co-pays, then the Gilead Advancing Access® co-pay coupon card can assist with covering up to $3,600/year for medication. No income eligibility requirement. Visit www.AdvancingAccessCopay.com or call 1-877-505-6986.
- If patient makes less than 400% FPL, then the Patient Advocate Foundation Co-Pay Relief Program can assist with covering up to $7,500/year for medication. Visit www.copays.com or call 866-512-3861.
- If patient makes less than 500% FPL, then the Patient Assistance Network Foundation can assist with covering up to $7,500/year for medication. As of December 2016, they were not accepting or processing new applications. Visit www.panfoundation.org or call 1-866-316-7263 to check availability.

For patients who do not have insurance:
- If patient has annual income of less than 500% FPL, then they might qualify for Gilead’s Advancing Access® Patient Assistance Program to receive medication, free of cost. Visit www.AdvancingAccessCopay.com or call 1-855-330-5479 between 9:00 a.m. and 8:00 p.m. (Eastern).
- The Partnership for Prescription Assistance (PPA) can assist uninsured individuals with getting medication at no or little cost. Visit www.pprax.org or call 1-888-4PPA-now (1-888-477-2669).

For the most current options available, visit: www.fairpricingcoalition.org/medication-assistance-program-and-co-pay-programsfor-prep.
9. What ongoing assessments are required for patients on Truvada® as PrEP?

Truvada® as PrEP should be prescribed as part of a comprehensive sexual health and HIV prevention plan. While patients are on Truvada®, the CDC Guidelines recommend the following:

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prevention and Medication Support</strong></td>
<td></td>
</tr>
<tr>
<td>Assess adherence</td>
<td>At every visit</td>
</tr>
<tr>
<td>Provide risk reduction counseling</td>
<td></td>
</tr>
<tr>
<td>Offer condoms</td>
<td></td>
</tr>
<tr>
<td>Manage side effects</td>
<td></td>
</tr>
<tr>
<td><strong>Laboratory Testing</strong></td>
<td></td>
</tr>
<tr>
<td>HIV testing</td>
<td>• Every 3 months; and&lt;br&gt;• Whenever there are symptoms of acute infection (serologic screening test Sexually transmitted infection (STI) symptom and HIV RNA test) screen and testing</td>
</tr>
<tr>
<td>Sexually transmitted infection (STI) symptom screen and testing:</td>
<td><strong>Symptom Screen:</strong>&lt;br&gt;• At every visit&lt;br&gt;<strong>Testing:</strong>&lt;br&gt;• At least every 6 months, even if asymptomatic (Note: Monogamous sero-discordant couples may not need STI screening as frequently)&lt;br&gt;• Whenever symptoms are reported</td>
</tr>
<tr>
<td>• NAAT (nucleic acid amplification test) to screen for gonorrhea and chlamydia, based on exposure site</td>
<td></td>
</tr>
<tr>
<td>• Rapid plasma reagin (RPR)</td>
<td></td>
</tr>
<tr>
<td>• Inspection for anogenital lesions</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C Antibody Test at least every 12 months.</td>
<td>At least every 12 months for: • MSM • Transgender persons • People who use drugs • People with multiple sexual partners</td>
</tr>
<tr>
<td>Serum creatinine and calculated creatinine clearance</td>
<td>At 3 months after initiation, then every 6 months</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Every 12 months</td>
</tr>
<tr>
<td>Pregnancy testing</td>
<td>Every 3 months</td>
</tr>
</tbody>
</table>

10. What services are billable?

Currently, there are no official ICD-9 or ICD-10 codes specifically for PrEP. Most private health insurance and Medicaid cover Truvada for PrEP but may require prior authorization. For a list of qualifying diagnoses codes, review the ‘Billing Codes’ table included in this packet or visit: [http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf](http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf).
Taking PEP means taking antiretroviral medicines (ART) after being potentially exposed to HIV to prevent becoming infected.

PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. If you think you’ve recently been exposed to HIV during sex, or through sharing needles and works to prepare drugs, or if you’ve been sexually assaulted, talk to your health care provider or an emergency room doctor about PEP right away.

**Is PEP right for me?**

If you’re HIV-negative or don’t know your HIV status, and in the last 72 hours you:

- think you may have been exposed to HIV during sex (for example, if the condom broke);
- shared needles and works to prepare drugs (for example, cotton, cookers, water); or
- were sexually assaulted, talk to your health care provider or an emergency room doctor about PEP right away.

PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. It is not a substitute for regular use of other proven HIV prevention methods, such as pre-exposure prophylaxis (PrEP), which means taking HIV medicines daily to lower your chance of getting infected; using condoms the right way every time you have sex; and using only your own new, sterile needles and works every time you inject.

PEP is effective, but not 100%, so you should continue to use condoms with sex partners and safe injection practices while taking PEP. These strategies can protect you from being exposed to HIV again and reduce the chances of transmitting HIV to others if you do become infected while you’re on PEP.

**I’m a health care worker, and I think I’ve been exposed to HIV at work. Should I take PEP?**

PEP should be considered if you’ve had a recent possible exposure to HIV at work. Report your exposure to your supervisor, and seek medical attention immediately.

Occupational transmission of HIV to health care workers is extremely rare, and the proper use of safety devices and barriers can help minimize the risk of exposure while caring for patients with HIV.

A health care worker who has a possible exposure should see a doctor or visit an emergency room immediately. PEP must be started within 72 hours after a recent possible exposure to HIV. The sooner, the better; every hour counts.

CDC issued updated guidelines in 2013 for the management of health care worker exposures to HIV and recommendations for PEP.

Clinicians caring for health care workers who’ve had a possible exposure can call the PEPlne (1-888-448-4911), which offers around-the-clock advice on managing occupational exposures to HIV, as well as hepatitis B and C. Exposed health care workers may also call the PEPlne, but they should seek local medical attention first.
**When should I take PEP?**
PEP must be started within 72 hours after a possible exposure. The sooner you start PEP, the better; every hour counts. Starting PEP as soon as possible after a potential HIV exposure is important. Research has shown that PEP has little or no effect in preventing HIV infection if it is started later than 72 hours after HIV exposure. If you’re prescribed PEP, you’ll need to take it once or twice daily for 28 days.

**Does PEP have any side effects?**
PEP is safe but may cause side effects like nausea in some people. These side effects can be treated and aren’t life-threatening.

**Where can I get PEP?**
Your health care provider or an emergency room doctor can prescribe PEP. Talk to them right away if you think you’ve recently been exposed to HIV.

**How can I pay for PEP?**
If you’re prescribed PEP after a sexual assault, you may qualify for partial or total reimbursement for medicines and clinical care costs through the Office for Victims of Crime, funded by the US Department of Justice.

If you’re prescribed PEP for another reason and you cannot get insurance coverage (Medicaid, Medicare, private, or employer-based), your health care provider can apply for free PEP medicines through the medication assistance programs run by the manufacturers. Online applications can be faxed to the company, or some companies have special phone lines. These can be handled urgently in many cases to avoid a delay in getting medicine.

If you’re a health care worker who was exposed to HIV on the job, your workplace health insurance or workers’ compensation will usually pay for PEP.

**Can I take a round of PEP every time I have unprotected sex?**
PEP should be used ONLY in emergency situations. PEP is not the right choice for people who may be exposed to HIV frequently—for example, if you often have sex without a condom with a partner who is HIV-positive. Because PEP is given after a potential exposure to HIV, more drugs and higher doses are needed to block infection than with PrEP, or pre-exposure prophylaxis. PrEP is when people at high risk for HIV take HIV medicines (sold under the brand name Truvada) daily to lower their chances of getting HIV. If you are at ongoing risk for HIV, speak to your doctor about PrEP.

Content provided by the US Centers for Disease Control and Prevention (CDC).
CENTERS FOR DISEASE CONTROL:

- CDC PrEP Basics:  
  www.cdc.gov/hiv/basics/prep.html

- CDC PrEP Resource information:  
  www.cdc.gov/hiv/risk/prep

- CDC PrEP Vitalsigns:  
  www.cdc.gov/vitalsigns/HIVPrEP

CONSUMER:

- AIDS.gov PrEP information:  
  www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/

- HIVe – offers consumer and provider resources on advancing reproductive and sexual wellness for individuals and families affected by HIV:  
  www.hiveonline.org

- International PrEP Resource – Where do you fit on the map? Learn more about access and advocacy:  
  www.prepwatch.org/

- National PrEP Provider Directory:  
  www.preplocator.org

- PrEP Houston:  
  www.prephouston.org

- Project Inform Informational Videos:  
  www.projectinform.org/prep/

FINANCE:

- Billing Codes Guide – offers providers a multitude of billing codes for HIV prevention including codes for PrEP, HIV screening, and linkage services:  

- Project Inform PrEP Flow Chart:  
GILEAD:

- Gilead PrEP Guidance for providers: start.truvada.com/hcp

LGBTQIA HEALTH:

- Resource to decrease the invisibility mask towards disparities and provision of important health care services for the LGBTQIA community. Also, serves as effective intervention for behavioral health concerns that may be related to experiences of anti LGBTQIA stigma.
- Spanish Version
- Providing Inclusive Services & Care for LGBT People

TRAINING:

- PrEP Clinician Consultation Center:
  www.nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis
- PrEP Clinician Warmline – offers up-to-date clinical consultation for PrEP decision-making:
  Phone: (855) 448-7737 or (855) HIV-PrEP
  Monday – Friday, 10 a.m. – 5 p.m. CST
- South Central AIDS Education & Training Center Program – offers training and clinical consultation around HIV/AIDS treatment and care management:
  www.aidseducation.org/offices-locations/hhs-houston
- Taking a Sexual History Guide:
  www.cdc.gov/STD/treatment/SexualHistory.pdf
- WHO PrEP Guidance:
  www.who.int/hiv/pub/guidance_prep/en/
Resources

To apply for health insurance on the federal exchange: www.healthcare.gov

Community Health Center Locator:
http://findahealthcenter.hrsa.gov/

**Washington state** (residents):
PrEP drug assistance program (PrEP-DAP)
http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP

**New York state** (residents):
PrEP assistance program (PrEP-AP)
Call 1-800-542-2437

Gilead Sciences:
Medication Assistance Program and Co-Pay Assistance
https://start.truvada.com/individual/truvadaprep-copay

Patient Advocate (PAF) Foundation:
Co-Pay Relief Program
https://www.copays.org/diseases/hiv-aids-and-prevention

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Division of HIV/AIDS Prevention,
National Center for HIV/AIDS,
Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027 USA
Phone: 800-232-4636

December 2015
Covering the Cost of PrEP Care

**Insured**
- Bill insurance
- Apply for copay assistance from Gilead or PAF

**Not insured**
- But may be eligible for Medicaid or ACA Plans

Apply

**Not eligible for Medicaid or ACA plans**
- OR
- Insurance denies claim

**Household Income 500% FPL or less**
- Gilead Medication Assistance Plan
- WA State Medication Assistance
- Care at CHC with sliding fee scale
- NY State PrEP Assistance Plan
- NY State PrEP Assistance Plan

**Household Income more than 500% FPL**
- Bill insurance
- Apply for copay assistance from Gilead or PAF

**PrEP Medication Assistance Program** (Gilead Sciences)

**People eligible for this program must:**
- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income ≤ 500% of the federal poverty level

**Once enrolled in this program:**
- Medication will be sent to the provider, a pharmacy, or the patient’s home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months by the provider

**PrEP Medication Assistance Program**

<table>
<thead>
<tr>
<th>Family Size</th>
<th>500% Federal Poverty Level Household Annual Income must be less than:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$58,850</td>
</tr>
<tr>
<td>2</td>
<td>$79,650</td>
</tr>
<tr>
<td>3</td>
<td>$100,450</td>
</tr>
<tr>
<td>4</td>
<td>$121,250</td>
</tr>
<tr>
<td>5</td>
<td>$142,050</td>
</tr>
<tr>
<td>6</td>
<td>$162,850</td>
</tr>
</tbody>
</table>

*Source: https://www.healthcare.gov/glossary/federal-poverty-level-FPL/

**Abbreviations**
- ACA - Affordable Care Act
- FPL - Federal Poverty Level
- CHC - Community Health Center
- PAF - Patient Advocate Foundation

**Definitions:**
- PrEP: Daily pill to prevent HIV infection (pre-exposure prophylaxis)
- Co-pay: Fixed amount to be paid by insured person per prescription
- Co-insurance: Fixed percentage of prescription cost to be paid by insured person
- Deductible: Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs