PRE-EXPOSURE PROPHYLAXIS FOR HIV
(EASIER THAN IT SOUNDS!)

Sean Kelly, MD
Vanderbilt Division of Infectious Diseases
August 10, 2018
Objectives

- Importance of PrEP in the Southeast
- Provider barriers for providing PrEP
- Becoming a PrEP provider
- Logistical considerations of a PrEP clinic
  - Visits
  - Labs
  - Truvada® access
  - Advertising
Have you provided PrEP?

A. Yes
B. No
C. Wait, what’s PrEP?
PrEP is primary prevention

It is intended to PREVENT the onset of a disease in those who are AT RISK

It is a concept, fulfilled by medication that has been FDA-approved for this purpose
But what is PrEP, really?

- **Truvada®**
  - Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtracitabine (FTC) 200mg
  - Developed by Gilead
  - FDA-approved for use as PrEP for adults on June 6, 2012
  - FDA-approved for use as PrEP for adolescents on May 15, 2018
- **Generic TDF/FTC approved 6/2017**

Also approved in Australia, Canada, France, Norway, Belgium, Netherlands, Peru, Israel, Kenya, Botswana, Zimbabwe and South Africa

*Coming soon in: Brazil, Nigeria, Zambia, Malawi, Uganda, India, Thailand, United Kingdom, Italy*
This is different from PEP

- PrEP = Pre-Exposure Prophylaxis
  - HIV exposure has not yet occurred
    - Indefinite duration if HIV risk persists
- PEP = Post-Exposure Prophylaxis
  - HIV exposure HAS occurred
  - Goal is to reduce incidence of established infection
  - THREE drugs required: Truvada® (TDF/FTC) + dolutegravir (or raltegravir)
    - Limited duration of 28 days
## Primary Prevention

**HIV**  
- Assess risk  
- Take a sexual history  
- Take a past medical, family, social history, check cholesterol and screen for diabetes,  
- Calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines  
- Laboratory evaluation: Serum creatinine, HIV screen  
- Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c  
- Further risk reduction: Health and counseling, STI screening  
- Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation  
- Medication options: Truvada®  
- Aspirin  
- Atorvastatin  
- Fluvastatin  
- Rosuvastatin  
- Pravastatin  
- Pitavastatin  
- Simvastatin

**Myocardial infarction**  
- Assess risk  
- Take a sexual history  
- Take a past medical, family, social history, check cholesterol and screen for diabetes,  
- Calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines  
- Laboratory evaluation: Serum creatinine, HIV screen  
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- Aspirin  
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- Fluvastatin  
- Rosuvastatin  
- Pravastatin  
- Pitavastatin  
- Simvastatin
Who benefits from PrEP

Anyone with high risk for HIV acquisition, as determined by the patient’s and/or provider’s assessment, in which the risk of Truvada® does not outweigh the benefit.

How well does PrEP work?
44% HIV risk reduction, but 92% risk reduction when taken consistently among MSM and transgender women
62.2% HIV risk reduction among heterosexual men and women
Partners PrEP Study Team

Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women


75% HIV risk reduction among heterosexual sero-discordant couples, 90% among those with detectable drug levels
Bangkok Tenofovir Study Group

Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, MDa, Dr Michael Martin, MDb, c, Pravan Suntharasamai, MDa, Udomsak Sangkum, MDa, Philip A Mock, MAppStatsb, Manoj Leethochawalit, MDc, Sithisat Chiamwongpaet, MDb, Praphan Kittisin, MDb, Pitinan Nattrjirote, MDb, Somyot Kittimunkong, MDb, Rutt Chuachowong, MDb, Roman J Gvetadze, MDb, Janet M McNicholl, MDb, c, Lynn A Paxton, MDb, Marcel E Curin, MDb, c, Craig W Hendrix, MDb, Suphak Vanichseni, MDa, for the Bangkok Tenofovir Study Group

48.9% risk reduction, but 74% HIV risk reduction when taken consistently, among IDUs (TDF only)
86% HIV risk reduction in MSM using on-demand PrEP
Dosing matters

Using drug concentrations in iPrEx and STRAND, pharmacokinetic models predict **76%** risk reduction with 2 doses/week, **96%** with 4 doses/week, and **99%** with 7 doses/week.

## Studies Summary

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Dosing</th>
<th>Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEX</td>
<td>MSM</td>
<td>Daily</td>
<td>44% (92% with ideal adherence)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Heterosexual men and women</td>
<td>Daily</td>
<td>62.2% (100% in open-label extension with regular follow-up)</td>
</tr>
<tr>
<td>Partners</td>
<td>Sero-discordant heterosexual couples</td>
<td>Daily</td>
<td>75% (90% with ideal adherence)</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study Group</td>
<td>Intravenous drug users</td>
<td>Daily</td>
<td>48.9% (74% with ideal adherence)</td>
</tr>
<tr>
<td>IPERGAY</td>
<td>MSM</td>
<td>On-demand</td>
<td>86%</td>
</tr>
</tbody>
</table>
Why PrEP matters
The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.
HIV Risk by Race/Ethnicity and MSM

White women: 1 in 880
White men: 1 in 132
Hispanic women: 1 in 227
Hispanic men: 1 in 48
Black women: 1 in 48
Black men: 1 in 20

White MSM: 1 in 11
Hispanic MSM: 1 in 4
Black MSM: 1 in 2

Tennessee
HIV risk and location of PrEP providers
Nashville
HIV risk and location of PrEP providers

https://aidsvu.org/state/tennessee/
https://getpreptn.com/get-prep/#map_top
PrEP Deserts

- Most MSM with reduced geographic access to PrEP providers ("PrEP deserts") reside in the South.
- Over 50% of MSM in the South must drive >60 minutes to a PrEP provider.
- PrEP deserts are generally non-urban areas.

Low PrEP Uptake

• Among recent national surveys, low numbers of primary healthcare providers reported providing PrEP (9%-35%).


The PrEP Care Cascade

- Many barriers exist along the PrEP care cascade.
- Patient-related barriers have been well-characterized across many different populations.
- Provider-related barriers are relatively poorly characterized, though they also exist along the care continuum.

Provider barriers

Knowledge/Attitudes

- Insufficient evidence of efficacy (22%-81%)
- Inexperience with Truvada/lack of knowledge (60%-77.5%)
- PrEP is cost-prohibitive (29%-92%)
- PrEP is not a primary care activity ("not me") (34%)
- Unfamiliarity with PrEP candidates; inability to assess high HIV risk (61%)

Provider barriers

Knowledge/Attitudes

• Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior) (33%)

• Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment) (67%)

• Patients perceived as non-adherent, and risk HIV resistance mutation development (40%-77%)

• Personal ideology

Provider Barriers

Needs for practice transformation

- Nursing support (92%)
- Social work support (90%)
- CME (90%)
- PrEP training event (OR 4.84, CI 1.77–13.21)

What are your barriers to providing PrEP?
As a society, we treat any HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.
…Ready for it?

• Inquiring about a sexual history and sexual health counseling are part of primary care.
  • *We already do that!*

• The most important tool for assessing HIV risk is your clinical sense.
  • *We already have that!*

• Basic labs are required for Truvada® prescriptions.
  • *We already do that!*

• Most common medications, like Truvada®, require follow-up and monitoring.
  • *We already do that!*
Get comfortable!

• Patients have sex, *in lots of different ways.*
• Patients may not want to discuss this.
• Providers may not feel comfortable discussing this.

Taking a sexual history is a potentially life-saving intervention.
HIV risk is behavioral

The only way to know is to ask (and listen)!
Taking a sexual history promotes comprehensive STI risk reduction counseling

Condom use
Knowing HIV status
Knowing partner’s HIV status
PrEP
Stigma

A preventative measure against the consequences of sexual activity

... condones sexual activity

... promotes sexual activity

... causes sexual activity
But actually…
No evidence of sexual risk compensation in the iPrEx trial of daily oral PrEP

For patients believing they were on PrEP, the number of receptive anal intercourse partners decreased.

For patients believing they were on PrEP, condom use increased.

Syphilis incidence also decreased in both study arms.
Ready, set, PrEP!
PrEP Clinic Needs

• Provider
• Nursing
  • Assistance in communicating with patient
  • Providing labs and other documents to pharmacy
  • Assisting in completing prior authorization
• Pharmacy
  • Specialty pharmacy partnership highly recommended
• Phlebotomy, blood draws
• Ability to provide treatment and counseling for STIs
Before prescribing

- Risk Evaluation and Mitigation Strategies (REMS)
  - REMS is a safety strategy to manage risks associated with a drug and to enable continued access to the drug by managing its safe use.
  - REMS is a safety measure beyond the professional labeling to ensure the drug’s benefits outweigh its risks.
  - REMS requirements are different for different drugs.
Before prescribing

- Risk Evaluation and Mitigation Strategies (REMS)

https://www.truvadapreprems.com/truvadaprep-resources
Before prescribing

https://www.truvadapreprems.com/truvadaprep-resources
Patient Intake

• Most new PrEP patients will seek out PrEP
• Since many have no PCP, allow self-referrals
• Consider patient insurance status
  • Cost of medication
  • Cost of quarterly visits
  • Cost of labs
  • Cost of vaccination, parenteral antibiotics and their administrations if patient acquires bacterial STI
PrEP Medication Counseling

- Dosing
  - One tab daily, with or without food
- Adherence, and its relationship to efficacy
- Time to effectiveness
  - 7-10 days for men, 21 days for women
  - Barrier protection especially needed during that time
- Adverse effects
  - Nausea, vomiting, diarrhea, loss of appetite, weight loss
  - Fatigue, headache
- Requirements for monitoring
- Refill process
  - “Call when you have 7-10 days left”
### Adverse Events

#### Table 2. Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>FTC–TDF (N = 1251)</th>
<th>Placebo (N = 1248)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of patients (%)</td>
<td>no. of events</td>
<td>no. of patients (%)</td>
</tr>
<tr>
<td>Any adverse event</td>
<td>867 (69)</td>
<td>2630</td>
<td>877 (70)</td>
</tr>
<tr>
<td>Any serious adverse event</td>
<td>60 (5)</td>
<td>76</td>
<td>67 (5)</td>
</tr>
<tr>
<td>Any grade 3 or 4 event</td>
<td>151 (12)</td>
<td>248</td>
<td>164 (13)</td>
</tr>
<tr>
<td>Grade 3 event</td>
<td>110 (9)</td>
<td>197</td>
<td>117 (9)</td>
</tr>
<tr>
<td>Grade 4 event</td>
<td>41 (3)</td>
<td>51</td>
<td>47 (4)</td>
</tr>
<tr>
<td>Elevated creatinine level</td>
<td>25 (2)</td>
<td>28</td>
<td>14 (1)</td>
</tr>
<tr>
<td>Headache</td>
<td>56 (4)</td>
<td>66</td>
<td>41 (3)</td>
</tr>
<tr>
<td>Nausea</td>
<td>20 (2)</td>
<td>22</td>
<td>9 (&lt;1)</td>
</tr>
<tr>
<td>Unintentional weight loss (≥5%)</td>
<td>27 (2)</td>
<td>34</td>
<td>14 (1)</td>
</tr>
</tbody>
</table>

**Death**

<table>
<thead>
<tr>
<th></th>
<th>FTC–TDF (N = 1251)</th>
<th>Placebo (N = 1248)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of events</td>
<td>no. of events</td>
<td>no. of events</td>
</tr>
<tr>
<td>Death</td>
<td>1 (&lt;1)‡</td>
<td>1</td>
<td>4 (&lt;1)</td>
</tr>
<tr>
<td>Discontinuation of study drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanently</td>
<td>25 (2)</td>
<td>26</td>
<td>27 (2)</td>
</tr>
<tr>
<td>Permanently or temporarily</td>
<td>79 (6)</td>
<td>99</td>
<td>72 (6)</td>
</tr>
</tbody>
</table>

*A listing of all laboratory abnormalities and clinical adverse events of grade 2 or higher that were reported in 25 or more subjects (1%) is provided in Tables S9 and S10 in the Supplementary Appendix. FTC–TDF denotes emtricitabine and tenofovir disoproxil fumarate.

† P values were calculated by the log-rank test.

‡ This death was due to a motorcycle accident.

iPrEX, 2010
## Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TDF-FTC (N=611)</th>
<th>Placebo (N=608)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of participants (%)</td>
<td>no. of events</td>
<td>no. of participants (%)</td>
</tr>
<tr>
<td>Any</td>
<td>557 (91.2)</td>
<td>4357</td>
<td>536 (88.2)</td>
</tr>
<tr>
<td>Any serious</td>
<td>63 (10.3)</td>
<td>68</td>
<td>66 (10.9)</td>
</tr>
<tr>
<td>Grade 3 or 4 only</td>
<td>19 (3.1)</td>
<td>21</td>
<td>29 (4.8)</td>
</tr>
<tr>
<td>At least possibly related to study drug</td>
<td>20 (3.3)</td>
<td>21</td>
<td>27 (4.4)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>231 (37.8)</td>
<td>285</td>
<td>243 (39.6)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>92 (15.1)</td>
<td>109</td>
<td>67 (11.0)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>155 (25.4)</td>
<td>235</td>
<td>156 (25.7)</td>
</tr>
<tr>
<td>Nausea</td>
<td>113 (18.5)</td>
<td>132</td>
<td>43 (7.1)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>69 (11.3)</td>
<td>87</td>
<td>43 (7.1)</td>
</tr>
</tbody>
</table>

| Back pain                               | 57 (9.3)        | 72             | 68 (11.2)   | 90            | 0.37      |
| Rash                                    | 39 (6.4)        | 44             | 42 (6.9)    | 48            | 0.81      |
| Fracture                                | 7 (1.1)         | 7              | 6 (1.0)     | 8             | 0.74      |
| Elevated creatinine                     | 1 (0.2)         | 1              | 0           | 0             | 1.00      |
| Hypophosphatemia                        | 142 (23.2)      | 219            | 159 (26.2)  | 245           | 0.65      |
| Hyperuricemia                           | 315 (51.6)      | 997            | 302 (49.7)  | 1017          | 0.45      |
| Elevated AST                            | 36 (5.9)        | 43             | 38 (6.2)    | 42            | 0.90      |
| Elevated ALT                            | 38 (6.2)        | 48             | 43 (7.1)    | 66            | 0.57      |
| Death†                                  | 2 (0.3)         | 2              | 4 (0.7)     | 4             | 0.45      |

*ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.
† All P values were calculated with the use of a time-to-first-event analysis (regression analysis of survival data on the basis of the Cox proportional-hazards model), with the exception of the P values for weight loss of 5% or more and death, which were calculated with the use of Fisher’s exact test.
‡ The causes of death in the TDF-FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).
Small (2%) but significant decline in estimated creatinine clearance was observed in the TDF/FTC group after taking the drug for, on average, 81 weeks.
Adverse Events

Table 3. Bone Mineral Density Scores.*

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Forearm</th>
<th>P Value</th>
<th>Hip</th>
<th>P Value</th>
<th>Lumbar Spine</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T score</td>
<td>TDF–FTC (N = 109)</td>
<td>Placebo (N = 112)</td>
<td>0.004</td>
<td>TDF–FTC (N = 109)</td>
<td>Placebo (N = 112)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

BUT THIS CAN RECOVER!

Bone mineral density recovered after 6 months of stopping TDF/FTC in both young and older adults.

| 24 mo | –0.87 | –0.13 | 0.20 | 0.76 | –1.09 | –0.28 |

* In the TDF–FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.
The First Visit

Initial Visit:
- Discuss PrEP with MD
- Provide labs
- Sign Truvada PrEP Agreement

PrEP is prescribed based on labs and your choice.

Pharmacist completes any necessary insurance requirements and sets you up with a copay card if possible.

PrEP is filled and shipped to you by Walgreens Specialty Pharmacy unless your insurance requires you to fill through a different pharmacy.
The First Visit

Agreement Form for Initiating Truvada® for Pre-exposure Prophylaxis (PrEP)

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

Healthcare Provider Agreement
By signing below, I signify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events. Specifically, I attest to having done the following:
- Confirmed the negative HIV-1 status of this person prior to starting TRUVADA for a PrEP indication
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of TRUVADA for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TRUVADA for a PrEP indication
- Reviewed the TRUVADA Medication Guide with the HIV-negative person at high risk prior to prescribing TRUVADA for a PrEP indication
- Completed the items on the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

HIV-Negative Person Agreement
By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of TRUVADA to reduce the risk of getting HIV-1 infection, and I understand them clearly. Specifically, I attest to the following:
- My healthcare provider talked with me about the importance of follow-up HIV-1 testing, and I agree to have repeat HIV-1 screening tests (at least every 3 months) as scheduled by my healthcare provider
- My healthcare provider talked with me about the safety risks involved with using TRUVADA to reduce the risk of getting HIV-1 infection
- My healthcare provider talked with me about a complete prevention strategy and always practicing safer sex by using condoms correctly
- I will talk with my healthcare provider if I have any questions
- I have read the TRUVADA Medication Guide

HIV-Negative Person’s Signature

Date

Healthcare Provider’s Signature

Date

https://www.truvadapreprems.com/truvadaprep-agreement-form#
The First Visit

• Labs:
  • HIV Ag/Ab
  • Basic Metabolic Panel
  • Hepatitis B sAg, sAb
  • Hepatitis C Ab
  • Treponemal IgG
  • Gonorrhea/chlamydia PCR
The First Visit

• Tips
  • If a specialty pharmacy will be used, make sure to document the patient’s preferred pharmacy
    • Provides more efficient prescription for azithromycin if +chlamydia!
  • Get contact information!
  • Taking a sexual history is an excellent opportunity to discuss substance use
  • High risk behavior often occurs during travel, so ASK!
  • Use patient-friendly terms
PrEP resources for patients

• PrEP welcome packet
  1. Truvada® medication guide
  2. CDC PrEP medication information sheet for patients
  3. Patient/Provider Agreement
  5. Walgreens Specialty Pharmacy contact information
  6. Additional PrEP resources
PrEP resources for patients

About Truvada

Truvada (tenofovir and emtricitabine) is a medication used to treat HIV infection. It is also used to prevent HIV infection. When you take Truvada to prevent HIV infection, this is called “pre-exposure prophylaxis” or “PrEP.”

How does Truvada help prevent HIV infection?

If you take Truvada daily, it can sometimes stop the virus from spreading throughout your body.

How should Truvada be used?

You must take one Truvada tablet once a day.

Follow the directions on your prescription label carefully. Ask your doctor or pharmacist for any information you do not understand.

Do not stop taking Truvada without talking to your doctor. When you start to take Truvada on your own, contact your doctor or pharmacist to get more.

You may be at higher risk of getting infected with HIV if you are taking Truvada on a regular basis.

Contact information:

Vanderbilt Comprehensive Care Center: (615) 322-1598

Agreement Form

For initiating Truvada® for Pre-Exposure Prophylaxis (PrEP)

Instructions:

Review the agreement form with a health care provider who is also taking Truvada for a PrEP indication at each visit. Fill in the parts in the patient’s medical record.

TRAUVADA is indicated in prophylaxis (PrEP) to reduce the risk of acquiring HIV. While you are on PrEP, you are at risk of acquiring HIV. You should use barrier methods of contraception.

Healthcare Provider Agreement

If you are not sure whether you want to take Truvada, you can consult with a healthcare provider or pharmacist to get more information.

Learn More About PrEP


CDC - HIV/AIDS and Prevention (http://www.cdc.gov/nchhstp/epi.html)

HIV/AIDS in the United States (https://www.cdc.gov/hiv/)


Project Online - Resources for preventing HIV (https://www.projectonline.com/)

Project Inform - Resources and materials for treating and preventing HIV/AIDS (https://www.projectinform.org/)

SAN Francisco AIDS Foundation (http://www.aidsfoundation.org/)

Support for PrEP: An Epidemic Interventions Initiative at the University of California (http://www.projectonline.com/)

Guidelines for Use of PrEP in Practice and Research Settings (http://www.aids.gov/research/prp/)

CDC - Centers for Disease Control and Prevention (https://www.cdc.gov/nchhstp/epi.html)

Vanderbilt University Medical Center (https://www.vanderbilthealth.com/preventive-care)

PrEP - Section 120: Acknowledges that taking PrEP is a personal choice, and that you are responsible for informing your healthcare provider of any side effects.

PrEP Watch - Interactive web page with information on getting access to PrEP (http://www.prpwatch.org/)

PrEPWatch: An Epidemic Interventions Initiative at the University of California (http://www.projectonline.com/)

Guidelines for Use of PrEP in Practice and Research Settings (http://www.aids.gov/research/prp/)

Vanderbilt University Medical Center (https://www.vanderbilthealth.com/preventive-care)
Prescribing process
Specialty Pharmacy

- Specialty Pharmacy may complete all prior authorization and copay assistance requirements and connect with the patient.
- May also send the prescription and prior authorizations to another pharmacy if the patient requests this.
Prescribing process

Specialty Pharmacy

• Send prescription electronically to Specialty Pharmacy
  • 30 tabs, 2 refills (total 90-day supply)
• When HIV screen and serum creatinine are available, send message to clinic RN to fax lab results to pharmacy
• Pharmacy contacts patient for further counseling and to arrange PrEP delivery
• Pharmacy contacts patient intermittently over 6 months to assess tolerability and adherence
Prescribing Process
No Specialty Pharmacy

• Send prescription to pharmacy
• Follow HIV screen, serum creatinine
• Complete PA if required (VERY few insurance companies still require this)
  • Information requested: last date of screening and sometimes PrEP Agreement form
• Copay card
  • Gilead copay card: $4800/year benefit
  • https://www.gileadadvancingaccess.com/copay-coupon-card
  • Federal beneficiaries not eligible
Prior Authorization

Drug Prior Authorization
entricitabine/tenofovir (TRUVADA)

STEP 1: CLEARLY PRINT AND COMPLETE TO EXPEDITE PROCESSING
Date: 02/28/2017
Prescriber First & Last Name: Sean Kelly

Patient First & Last Name:

Patient Address:

Patient ID:

Patient Date of Birth:

STEP 2: COMPLETE REQUIRED CRITERIA: COMPLETE ONE OF THREE
DIAGNOSIS A: Coverage for Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV) Infected patients (Approve for Lifetime)
☐ Prescribed for the active treatment of HIV or HBV

DIAGNOSIS B: Post-Exposure Prophylaxis (Approve for 1 Month)
☐ Prescribed for post-exposure prophylaxis following suspected or confirmed Human Immunodeficiency Virus (HIV) exposure

DIAGNOSIS C: Pre-Exposure Prophylaxis (Initial Coverage) (Approve for 3 Months)
☐ Patient is at high risk for contracting Human Immunodeficiency Virus (HIV) due to sexual transmission and receiving TRUVADA for pre-exposure prophylaxis. If not due to sexual transmission, please explain other reason patient is at high risk for contracting HIV.

AND ☐ Patient is ≥ 18 years of age
AND ☐ Patient is HIV negative: Please provide date of last test.
AND ☐ Prescriber has completed the REMS Prescriber Checklist: http://www.truvadaprems.com/Content/pdf/Checklist_for_Prescribers.pdf
AND ☐ Patient and prescriber have signed the REMS Agreement Form and it is saved in the patient's medical chart: http://www.truvadaprems.com/Content/pdf/Agreement_Form.pdf
Please provide expected duration of treatment:

DIAGNOSIS D: Pre-Exposure Prophylaxis (Continuing Coverage) (Approve for 3 Months)
☑ Patient is Human Immunodeficiency Virus (HIV) negative
Please provide date of last test: 12/30/2018

STEP 3: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-668-8161
Prescriber Signature: Sean Kelly
Date: 2-28-17

If patient meets criteria, allow 2 business days for processing
Other Cost Options

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

YES

1. Gilead Advancing Access Co-pay Card
gileadcopay.com
877-505-5965
- $3,600 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- Must be US resident
- Not available for persons with Medicare, Medicaid, VA or other state/federal prescription drug programs.

2. Patient Access Network Foundation
panfoundation.org/vir-treatment-and-prevention
866-315-7763
- $8,000 max/year, re-apply
- Income <50% FPL ($50,300)
- Based on taxable income (1040 Line 2, 1040 EZ Line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAF Foundation directly

3. Patient Advocate Foundation (PAF)
https://www.paf.org/our-services-and-prevention
- $5,500 max/year, re-apply
- Income <60% FPL ($48,240)
- Based on taxable income (1040 Line 7, 1040 EZ Line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- US resident
- Pharmacies can’t bill PAF Foundation directly
- Case managers available to help resolve medical costs issues (800-833-2742)

NO

U.S. RESIDENT?

NO

NON-RESIDENT/UNDocumented?

NO

IF NO

Enroll in an Insurance Marketplace
obamacarefacts.com/state-health-insurance-exchange/
Avoid Bronze plans if you can, they generally have higher costs.
Silver plans will offer lower costs for people earning up to 250% FPL ($30,150), Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

IF YES

Enroll in the Gilead MAP.
www.truvada-patient-assistance.com

Enroll in the Gilead MAP.
www.truvada-patient-assistance.com

Special enrollment
You can get insurance during the month of the year "qualifying life events" such as pregnancy, loss of employment, change in income, marriage, etc.

On Medicaid?
Medicaid may cover some medical costs related to PrEP if you encounter barriers to coverage, consult a legal advocate.

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FSAs (Flexible Spending Accounts)
Employees can use FSAs, it can help cover up to $2,550 of out-of-pocket costs.

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If you’re a resident, these state plans may also help:
- CO: https://www.colorado.gov/pd/PrEP
- IL: https://www.lid.Cole/PrEP
- MA: https://www.mass.gov/truvoa/PrEP
- WA: https://www.wa.gov/hca/PrEP
- NH: https://health.hrsa.gov/PrEP
- RI: https://www.rh.gov/PrEP

UPDATE AS OF:
FEBRUARY 10, 2017

Billing/coding

- While ICD-10 does not provide specific codes for PrEP, the following codes have been discussed with billing and used for PrEP visits:
  - Z20.6 “Contact with and (suspected) exposure to HIV ”
  - Z17.1 “Human immunodeficiency virus [HIV] counseling”
  - Z11.3 “ Encounter for screening for infection with a predominantly sexual mode of transmission”
  - Z79.2 “Long-term (current) use of antibiotics”

- Note: Can also bill by time, >25 minutes = level 4

- Not suggested:
  - Z72.52 – High risk homosexual behavior
The Second Visit

- Repeat HIV screen, repeat serum creatinine
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- Assess pregnancy intention (test if could be pregnant)
- If HIV-negative and eligible, refill PrEP
Every 3 months

- HIV screen
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- Assess pregnancy intention (test if could be pregnant)
- If HIV-negative and eligible, refill PrEP
Every 6 months

- Screen for other STIs
- Repeat serum creatinine
STOP PrEP

• The patient doesn’t want it
• Behavior or life situations have changed that lower risk for HIV infection
• Intolerable adverse events/toxicities
• Nonadherence despite attempted interventions to improve
• HIV-infection
## A year of PrEP

<table>
<thead>
<tr>
<th>Encounter</th>
<th>To do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 0</td>
<td>• Screen for HIV</td>
</tr>
<tr>
<td></td>
<td>• Confirm HBV and HCV status</td>
</tr>
<tr>
<td></td>
<td>• Check serum creatinine</td>
</tr>
<tr>
<td></td>
<td>• Screen for STIs</td>
</tr>
<tr>
<td></td>
<td>• Counseling</td>
</tr>
<tr>
<td></td>
<td>• Prescribe</td>
</tr>
<tr>
<td>Month 3</td>
<td>• Screen for HIV</td>
</tr>
<tr>
<td></td>
<td>• Check serum creatinine</td>
</tr>
<tr>
<td></td>
<td>• Counseling</td>
</tr>
<tr>
<td></td>
<td>• Prescribe</td>
</tr>
<tr>
<td>Month 6</td>
<td>• Screen for HIV</td>
</tr>
<tr>
<td></td>
<td>• Screen for STIs</td>
</tr>
<tr>
<td></td>
<td>• Counseling</td>
</tr>
<tr>
<td></td>
<td>• Prescribe</td>
</tr>
<tr>
<td>Month 9</td>
<td>• Screen for HIV</td>
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<tr>
<td></td>
<td>• Check serum creatinine</td>
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<tr>
<td></td>
<td>• Counseling</td>
</tr>
<tr>
<td></td>
<td>• Prescribe</td>
</tr>
<tr>
<td>Month 12</td>
<td>• Screen for HIV</td>
</tr>
<tr>
<td></td>
<td>• Screen for STIs</td>
</tr>
<tr>
<td></td>
<td>• Counseling</td>
</tr>
<tr>
<td></td>
<td>• Prescribe</td>
</tr>
</tbody>
</table>

### Labs:
- HIV screen: 5
- Serum creatinine: 3
- STI screen: 3

### Prescriptions/Refill authorizations: 5

### Discussions: 5+
Pre-Exposure Prophylaxis (PrEP) at the Vanderbilt Comprehensive Care Center

If you have a partner who is not HIV-infected, the Vanderbilt Comprehensive Care Center now offers pre-exposure prophylaxis (PrEP) to reduce his or her risk of HIV infection.

PrEP is an HIV-prevention strategy. It is a pill, taken once daily, containing some of the same medications used to treat HIV. If taken by an HIV-uninfected person who has a high risk of getting HIV, PrEP may reduce that person’s risk by more than 90%.

If your partner is interested, he or she may set up an appointment with a Vanderbilt Comprehensive Care Center PrEP provider by calling 615-875-5111.

Combination therapy PrEP offers effective way to prevent HIV infection

by Bh Snyder | Thursday, Sep. 7, 2017, 9:44 AM

Infectious disease experts Katie White, M.D., Ph.D., and Sean Kelly, M.D., are working to raise awareness of effective ways to prevent HIV infection, including the combination drug therapy called pre-exposure prophylaxis, or PrEP. (photo by Daniel De Chiefs)

Rates of new HIV infections in the United States are declining — except among men who have sex with men. Rates are particularly high among African-American and Hispanic men and especially in the South.
PrEP Locator

PrEP Locator Find Your Provider

About Us  About PrEP  Locator Data  FAQ  Add Provider  Add Locator To Your Site  Contact

Zip code or city & state, or full address

- PrEP for uninsured
- PrEP access assistance

Vanderbilt Infectious Disease Clinic
1211 21st Avenue S
Medical Arts Building
Nashville, TN 37212
615-936-1174
Distance from your location: 0.3 miles

Planned Parenthood Nashville Health Center
412 Dr. D.B. Todd Jr. Blvd
Nashville, TN 37203
615-221-7216
Distance from your location: 1.4 miles

Meharry Community Wellness Center
1005 Dr. D.B. Todd Jr. Blvd
Suite 333
Nashville, TN 37209
615-327-1481
Distance from your location: 2 miles

Middle Tennessee Internal Medicine Associates - Tracy Osbourne MD
510 Recovery Road
Suite 201
Nashville, TN 37212
615-203-7080
Distance from your location: 6 miles

Neighborhood Health @ MyHouse
42 Metroplex Drive
Building 4
Nashville, TN 37211

Add PrEP Locator to Your Site
Support a provider for the directory

https://preplocator.org
Conclusion

• PrEP is an extremely effective preventive strategy
• Many PrEP barriers exist, but can easily be overcome
• Understand PrEP prescribing guidelines
• Evaluate individual clinic needs
• Identify individual beliefs and perceptions
• Ask for help!

sean.g.kelly@vanderbilt.edu
Questions?