Pre-Exposure Prophylaxis for HIV (it’s easier than it sounds)

Anna K. Person
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Special thanks to Dr. Sean Kelly
Vanderbilt Division of Infectious Diseases
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
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?

- Right now, PrEP is Truvada®
  - Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg
  - Developed by Gilead
  - FDA-approved for use as PrEP on June 6, 2012
- 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) + dolutegavir
    • Limited duration of 28 days
## Primary Prevention

<table>
<thead>
<tr>
<th>HIV</th>
<th>Myocardial infarction or Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assess risk</strong></td>
<td>Take a sexual history</td>
</tr>
<tr>
<td><strong>Laboratory evaluation</strong></td>
<td>Serum creatinine, HIV screen</td>
</tr>
<tr>
<td><strong>Further risk reduction</strong></td>
<td>Condom use, sexual health and substance use counseling, STI screening</td>
</tr>
<tr>
<td><strong>Medication options</strong></td>
<td>Truvada®</td>
</tr>
</tbody>
</table>
How well does PrEP work?
44% HIV risk reduction, but 92% risk reduction when taken consistently among MSM and transgender women
TDF2 Study Group

Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana

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
48.9% risk reduction, but 74% HIV risk reduction when taken consistently, among IDUs (TDF only)
On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

Jean-Michel Molina, M.D., Catherine Capitant, M.D., Bruno Spire, M.D., Ph.D., Gilles Pialoux, M.D., Laurent Cotte, M.D., Isabelle Charreau, M.D., Cécile Tremblay, M.D., Jean-Marie Le Gall, Ph.D., Eric Cua, M.D., Armelle Pasquet, M.D., François Raffi, M.D., Claire Pintado, M.D., Christian Chidiac, M.D., Julie Chas, M.D., Pierre Charbonneau, M.D., Constance Delaugerre, Pharm.D., Ph.D., Marie Suzan-Monti, Ph.D., Benoîte Loze, B.S., Julien Fonsart, Pharm.D., Gilles Peytavin, Pharm.D., Antoine Cheret, M.D., Ph.D., Julie Timsit, M.D., Gabriel Girard, Ph.D., Nicolas Lorente, Ph.D., Marie Préau, Ph.D., James F. Rooney, M.D., Mark A. Wainberg, Ph.D., David Thompson, B.C.L., LL.B., Willy Rozenbaum, M.D., Veronique Doré, Ph.D., Lucie Marchand, B.S., Marie-Christine Simon, B.S., Nicolas Etien, B.S., Jean-Pierre Aboulker, M.D., Laurence Meyer, M.D., Ph.D., and Jean-François Delfraissy, M.D., for the ANRS IPERGAY Study Group


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%</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

Who benefits from PrEP?
CDC Recommendations (for MSM)

• Adult man
• Without acute or established HIV infection
• Any male sex partners in past 6 months
• Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following
• Any anal sex without condoms (receptive or insertive) in past 6 months
• Any STI diagnosed or reported in past 6 months
• Is in an ongoing sexual relationship with an HIV-positive male partner

CDC Recommendations (for heterosexual men and women)

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

**AND at least one of the following**

- Is a man who has sex with both women and men (behaviorally bisexual)
- 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

CDC Recommendations (for IDU)

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months
  
  **AND at least one of the following**

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition

Who benefits from PrEP?

- Sero-discordant sexual activity (couples)
- Multiple sex partners (especially sex partners with unknown HIV status or at risk for HIV) with inconsistent or no condom use
- History of sexually transmitted infections
- Exchange of sex for money or commodities
- Injection drug use
- Study out of Chicago, 300 HIV neg MSM for 3 years, of those who contracted HIV only 49% met CDC criteria for PrEP
- Anyone who has sex in the South? Clinical judgement!
Who doesn’t benefit?

• HIV infection
• Those at risk for adverse effects due to pre-existing comorbid conditions (chronic kidney disease)
• Unwilling to take daily medication
• Not engaging in activity with increased HIV risk
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
Stigma

• PrEP is a “party drug”
• PrEP promotes “bareback sex”
• PrEP users will stop using condoms
• PrEP users will acquire more STIs
But actually...

Pre-Contemplation

Maintenance

Active
Confidence in
Stronger
Fewer sexual
Further risk reduction

Contemplation

Planning
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.

What are your barriers to providing PrEP?
Provider barriers

Knowledge

• Inexperience with Truvada/lack of knowledge (60%-77.5%)$^{3,6,8,10}$

• Insufficient evidence of efficacy (22%-81%)$^{5,6,7,11}$

• PrEP is cost-prohibitive (29%-92%)$^{4,5,6,7,10}$

• Unfamiliarity with PrEP candidates (inability to assess high HIV risk) (61%)$^6$
Provider barriers
Perception/Attitudes

• Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior) (33%)\textsuperscript{2,4}
• Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment) (67%)\textsuperscript{5,7}
• Patients perceived as non-adherent, and risk HIV drug resistance selection (40%-77%)\textsuperscript{4,5,7,11}
• PrEP is not a primary care activity (“not me”) (34%)\textsuperscript{4,5}
• Personal ideology\textsuperscript{5}
Provider barriers

Behavior

- Low number of providers reported providing PrEP (9%-35%)\textsuperscript{5,8}
Provider Barriers

Needs for practice transformation

• Nursing support (92%)\(^6\)
• Social work support (90%)\(^6\)
• CME (90%)\(^6\)
• PrEP training event (OR 4.84, CI 1.77–13.21)\(^8\)
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.
  – You already do that!
• The most important tool for assessing HIV risk is your clinical sense.
  – You already have that!
• Basic labs are required for Truvada prescriptions.
  – You already do that!
• Most common medications, like Truvada, require follow-up and monitoring.
  – You already do that!
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

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**Initiation of Truvada® for Pre-exposure Prophylaxis (PrEP)**

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

<table>
<thead>
<tr>
<th>Lab Tests/Evaluation</th>
<th>Counseling/Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Completed high risk evaluation of uninfected individual</td>
<td>□ Discussed known safety risks with use of TRUVADA for a PrEP indication</td>
</tr>
<tr>
<td>□ Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication</td>
<td>□ 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</td>
</tr>
<tr>
<td>- If clinical symptoms consistent with acute viral infection are present and recent (&lt;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 is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive)</td>
<td>□ Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants</td>
</tr>
<tr>
<td>□ Performed HBV screening test</td>
<td>□ Counseled on the importance of adherence to daily dosing schedule</td>
</tr>
<tr>
<td>□ Confirmed estimated creatinine clearance (CrCl) &gt;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 assess potential risks and benefits of continued use</td>
<td>□ Discussed that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention strategy</td>
</tr>
<tr>
<td>□ Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HIV medications</td>
<td>□ Educated on practicing safer sex consistently and using condoms correctly</td>
</tr>
<tr>
<td>□ Evaluated risk/benefit for women who may be pregnant or may want to become pregnant</td>
<td>□ Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)</td>
</tr>
<tr>
<td></td>
<td>□ Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission</td>
</tr>
<tr>
<td></td>
<td>□ Offered HBV vaccination as appropriate</td>
</tr>
<tr>
<td></td>
<td>□ Provided education on where information about TRUVADA for a PrEP indication can be accessed</td>
</tr>
<tr>
<td></td>
<td>□ Discussed potential adverse reactions</td>
</tr>
<tr>
<td></td>
<td>□ Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk</td>
</tr>
</tbody>
</table>

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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>
<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>
</tbody>
</table>

<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>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>

<table>
<thead>
<tr>
<th></th>
<th>FTC–TDF (N = 1251)</th>
<th>Placebo (N = 1248)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (&lt;1)‡</td>
<td>1</td>
</tr>
<tr>
<td>Discontinuation of study drug</td>
<td>25 (2)</td>
<td>26</td>
</tr>
<tr>
<td>Permanently</td>
<td>25 (2)</td>
<td>26</td>
</tr>
<tr>
<td>Permanently or temporarily</td>
<td>79 (6)</td>
<td>99</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.
# 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>385</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>215</td>
<td>155 (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>
<tr>
<td>Back pain</td>
<td>57 (9.3)</td>
<td>72</td>
<td>68 (11.2)</td>
</tr>
<tr>
<td>Rash</td>
<td>39 (6.4)</td>
<td>44</td>
<td>42 (6.9)</td>
</tr>
<tr>
<td>Fracture</td>
<td>7 (1.1)</td>
<td>7</td>
<td>6 (1.0)</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>1 (0.2)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>142 (23.2)</td>
<td>219</td>
<td>159 (26.2)</td>
</tr>
<tr>
<td>Hyperamylasemia</td>
<td>315 (51.6)</td>
<td>997</td>
<td>302 (49.7)</td>
</tr>
<tr>
<td>Elevated AST</td>
<td>36 (5.9)</td>
<td>43</td>
<td>38 (6.2)</td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>38 (6.2)</td>
<td>48</td>
<td>43 (7.1)</td>
</tr>
<tr>
<td>Death‡</td>
<td>2 (0.3)</td>
<td>2</td>
<td>4 (0.7)</td>
</tr>
</tbody>
</table>

* 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>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>T score</td>
<td></td>
<td>0.004</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></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.

* 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

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
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 Ag/Ab 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
• Fax HIV Ag/Ab, serum creatinine when available
• Complete PA if required
  – Information requested: last date of screening and sometimes PrEP Agreement form
• Copay card
  – Gilead copay card: $3600/year benefit
  – https://www.gileadadvancingaccess.com/copay-coupon-card
  – Federal beneficiaries not eligible
Prior Authorization

Drug Prior Authorization
etricitabine/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**: 
- **Prescriber NPI**: 1832477171
- **Patient Address**: 1211 21st Ave S Suite 102A Nashville TN 37212
- **Prescriber Address**: 
- **Patient ID**: 
- **Prescriber Phone**: 615-306-1174
- **Patient Date of Birth**: 
- **Prescriber Fax**: 615-375-6886

**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)
  - [ ] For patients who are HIV positive or HBV positive
  - [ ] 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**: Pro-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:
  - [ ] Patient is ≥ 18 years of age
  - [ ] Patient is HIV negative: Please provide date of last test:
  - [ ] Prescriber has completed the REMS Prescriber Checklist:
  - [ ] Patient and prescriber have signed the REMS Agreement Form and it is saved in the patient's medical chart:
  - 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: 12/30/2011

**STEP 3: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-566-8551**

- **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
   877-505-5985
   - $3,600 max/calendar year
   - No income restrictions
   - Covers co-pays, deductibles and co-insurance
   - Re-apply annually as needed
   - US resident
   - Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs
   If pharmacy is unable to access Gilead's Co-pay Card, keep sales and pharmacy receipts. Call Gilead copay line for reimbursement for a refill. Some restrictions apply. Terms and conditions at gileadcopay.com.

2. Patient Access Network Foundation
   patientaccessfoundation.org/ivtreatment-and-prevention
   866-316-7763
   - $5,200 max/year, re-apply
   - Income <50% FPL ($50,300)
   - Based on taxable income (1040 line 2, 1040EZ line 1)
   - Must be insured (as listed under "YES" above)
   - Covers co-pays, deductibles and co-insurance
   - US resident
   - Pharmacies can bill PAN Foundation directly
   These programs may be subject to funding shortfalls, which may limit enrollment.

3. Patient Advocate Foundation (PAF)
   https://www.paf.org/chronicillness-and-prevention/
   - $5,700 max/year, re-apply
   - Income <40% FPL ($48,240)
   - Based on taxable income (1040 line 2, 1040EZ line 1)
   - Must be insured (as listed under "YES" above)
   - Covers co-pays only
   - Not for US residents (utility bill, etc.)
   - Case managers available to help resolve medical costs issues (800-553-5274)

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31

FEB 1 – OCT 31

below 120% FPL/yr ≤ ($11,440)

above 138% FPL/yr > ($11,440)

Enroll in an insurance marketplace

obamacarefacts.com/state-health-insurance-exchange/

Avoid Bronze plans if you can generally have higher costs.

Silver plans will offer lower cost 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.

MON-RESIDENT/ UNDOCUMENTED?

Check if you’re eligible for your state Medicaid plan.

IF NO

What’s your income?

below 60,000

above 60,000

Enroll in the Gilead MAP.

www.truvada.com/truvada-patient-assistance

50% off Truvada (1375 FPL-152%) and Truvada + Descovy (100% off FPL-120%) and Truvada (1040 line 2, 1040EZ line 1)

Inquire about costs –
https://www.gilead.com/PrEP/insurance/

On Medicaid?

Medicaid users can file medical costs related to PrEP if you encounter barriers to coverage. Consult legal advocate.

FSA (flexible spending account)

If employer offers an FSA, it can help cover up to $2,750 of out-of-pocket costs.

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>
</table>
| Month 0   | • Screen for HIV  
           | • Confirm HBV and HCV status  
           | • Check serum creatinine  
           | • Screen for STIs  
           | • Counseling  
           | • Prescribe |
| Month 3   | • Screen for HIV  
           | • Check serum creatinine  
           | • Counseling  
           | • Prescribe |
| Month 6   | • Screen for HIV  
           | • Screen for STIs  
           | • Counseling  
           | • Prescribe |
| Month 9   | • Screen for HIV  
           | • Check serum creatinine  
           | • Counseling  
           | • Prescribe |
| Month 12  | • Screen for HIV  
           | • Screen for STIs  
           | • Counseling  
           | • Prescribe |

**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 in starting PrEP, he or she may set up an appointment with a Vanderbilt Comprehensive Care Center PrEP provider by calling 615-875-5111.
PrEP Locator

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
- Anna.k.person@vanderbilt.edu
References