

HIV TAC TEAM



**Practical Strategies for Implementing PrEP in
Primary Care Setting**

Presenter: Jeffrey Klausner
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Pre-Exposure Prophylaxis (PrEP) for HIV Infection

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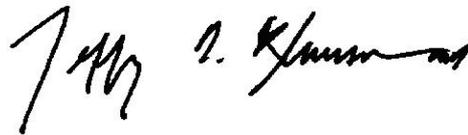
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Disclosures

- Dr. Klausner is a faculty member of the University of California Los Angeles
- Dr. Klausner is a guest researcher with the US CDC Mycotics Diseases Branch
- Dr. Klausner is a member of the WHO STD Guidelines group
- Dr. Klausner is a board member of YTH, Inc, non-profit
- Dr. Klausner is unpaid medical advisor for Healthvana.com

- In the past 12 months, Dr. Klausner and UCLA Regents have received:
 - Research funding, supplies or unrestricted gifts from the NIH, CDC, DOD, Hologic, Gilead Sciences, Cepheid, Standard Diagnostics, MedMira, AIDS Healthcare Foundation, and Sentient Research

A handwritten signature in black ink, appearing to read "J. Klausner".

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Learning Objectives

- Increase participant's knowledge of the effectiveness and safety of Truvada for PrEP
- Enhance participant's capacity to identify those who would benefit from Truvada for PrEP
- Understand when to prescribe Truvada for PrEP and manage drug and behavioral side effects

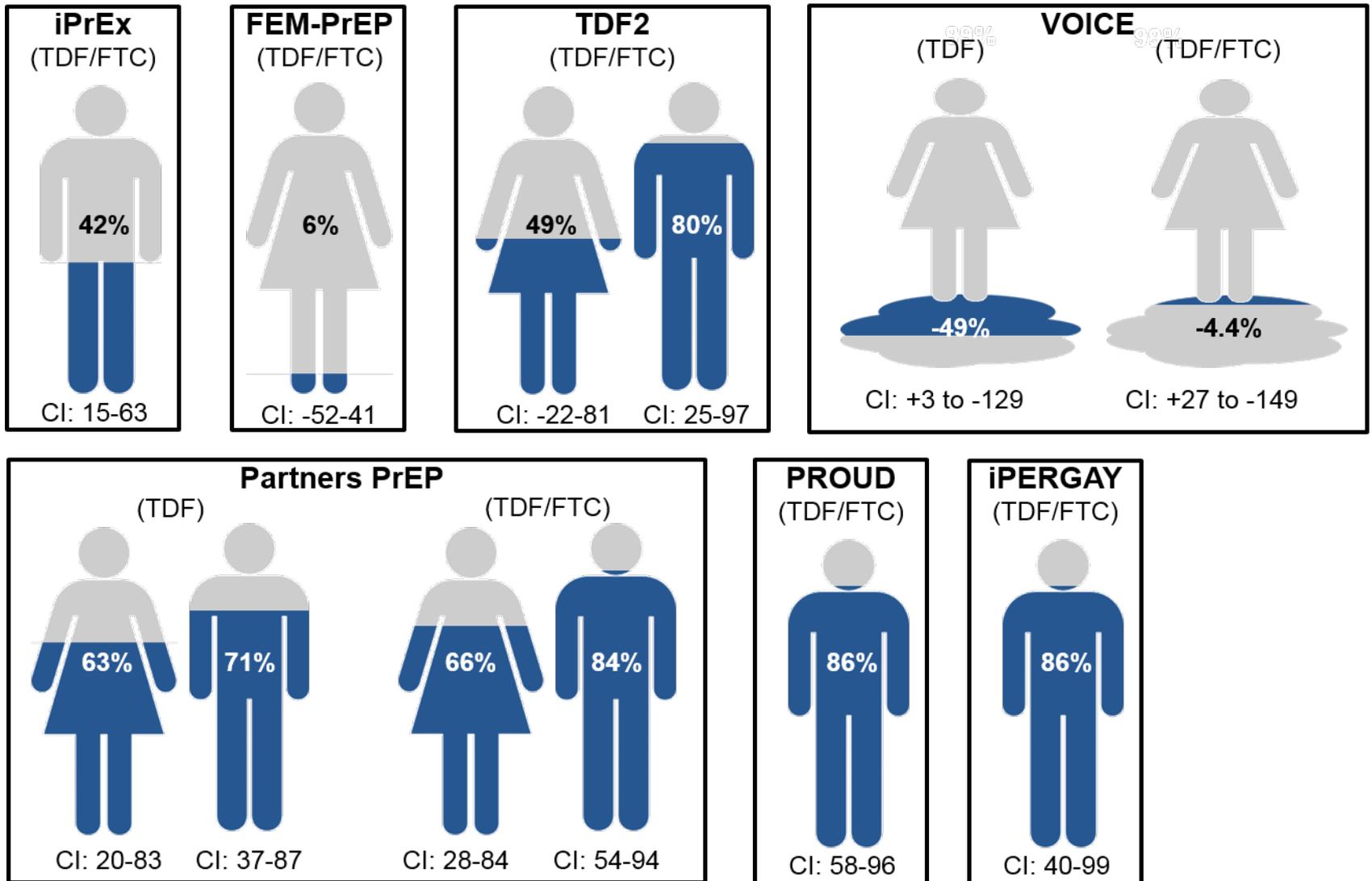
Outline

- What is PrEP?
- How well does it work?
- Is it safe?
- Offering PrEP
- Cases
- Resources

What is PrEP?

- Truvada (emtricitabine/tenofovir) (FTC-3TC)
- One pill, once a day
- FDA-approved, July 2012

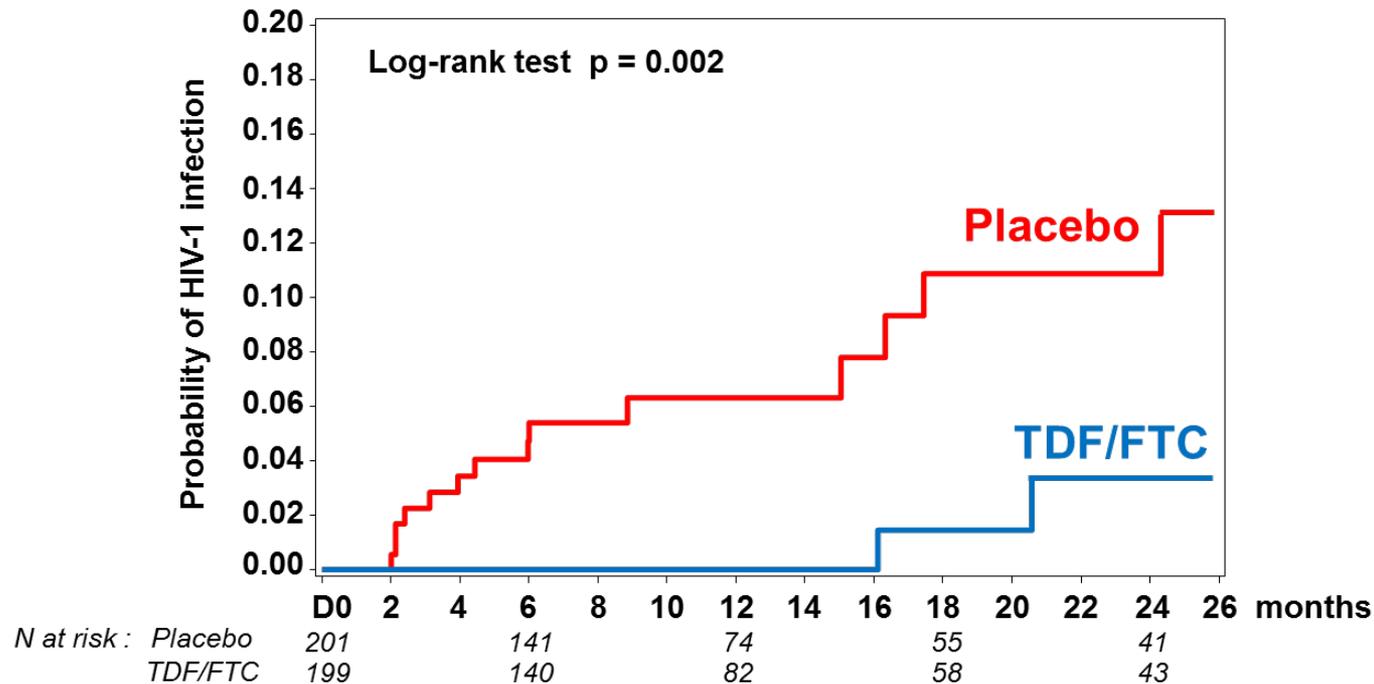
Effectiveness of Truvada



Slide courtesy of Raphael Landovitz, MD, UCLA, March 2015

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Effectiveness in iPERGAY study



Mean follow-up of 13 months: 16 subjects infected

14 in placebo arm (incidence: 6.6 per 100 PY), **2 in TDF/FTC arm** (incidence: 0.94 per 100 PY)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, $p=0.002$)

NNT for one year to prevent one infection : 18

Molina JM, CROI 2015, Abstract 23LB

Safety of Truvada

- Clinical
 - Mild short-term nausea +/- diarrhea (10%)
 - Decreased appetite + weight loss (5-10%)
 - Reversible small decrease in bone density (1%)
 - Reversible small decrease in kidney function (0.5%)
- Sexual health
 - Decrease in condom use
 - Increase in syphilis and rectal gonorrhea and chlamydia

Key Steps in a PrEP Program

- Identify the population at risk – young men who have sex with men, men who have sex with men of color, men who have sex with men attending STD clinics, sex workers, sex partners of injection drug users
- Identify the clinical setting for care
- Assemble a multi-disciplinary team—medical provider (MD, NP, PA), social worker, phlebotomist, other health workers
- Create protocols for inclusion, exclusion, quarterly follow-up and testing (clinical and STD)
- Educate and outreach to target community
- Enrollment—informed consent
- Adherence support—OregonReminders.org
- Monitoring and evaluation

Adapted by JD Klausner from GW Daughtridge, et al., ID Special Edition, 2015

Routine HIV Testing 101

- HIV testing should be routine
- CDC recommends all persons age 13-64 years undergo at least 1 HIV test
- MSM and those with > 1 partner at least annual testing, often 2-4x/ year
- Clinic policy should be all patients undergo HIV testing, unless patient declines (“opt out”)

Smith R et al. Beyond the end of exceptionalism: integrating HIV testing into routine medical care and HIV prevention. Expert Rev Anti Infect Ther. 2007 Aug;5(4):581-9.

Case 1

- 22 year old man, recent syphilis treatment, reports sex with other men
- Tested HIV-negative 2 months ago
- What additional history is needed?
- What tests are needed?
- Should Truvada for PrEP be prescribed?

Identify those at HIV risk

- **Men who have sex with men**
 - Ask every man if they have had sex with men, women or both in past 12 months
 - If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
 - Steady, main partner
 - If has main partner, ask about monogamy or sexual agreement
 - Regular, occasional partners
 - Casual, anonymous partners
 - Ask about where he meets partners—clubs, online, etc.
 - Any exchange of money/drugs for sex

CDC Recommended Indications for PrEP Use by Men who have Sex with Men

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see heterosexual criteria)
- 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

US Public Health Service “Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2014”

Case 2

- 42 year old woman with HIV-infected partner
- Partner's viral load is unknown
- Has condomless sex when he's in town
- Is Truvada for PrEP indicated?
- Risks vs. benefits?
- Baseline history and testing?

Identify those at HIV risk

- **Women**

- Ask every woman if they have had sex with men, women or both in past 12 months
- If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
 - Steady, main partner
 - If has main partner, ask about HIV status
 - Ask if main partner has other partners or other male partners
 - Regular, occasional partners
 - Casual, anonymous partners
- Any exchange of money/drugs for sex
- Injection drug use

Identify those at HIV risk (cont.)

- **Men who have sex with women**
 - If sexually active with women, ask about types of partnerships, relationships and HIV status of partners:
 - Steady, main partner
 - If has main partner, ask about HIV status/ injection drug use
 - Regular, occasional partners
 - Casual, anonymous partners
 - Any exchange of money/drugs for sex
 - Injection drug use

CDC Recommended Indications for PrEP Use by heterosexually active 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) [also evaluate indications for PrEP use by MSM criteria]
- 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

US Public Health Service “Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2014”

Identify those at HIV risk

- **Transgender Adults**

- Ask every person their gender identity.
- Ask every person if they have had sex with men, women or both in past 12 months.
- If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
 - Steady, main partner
 - If has main partner, ask about HIV status
 - Ask if main partner has other partners or other male partners
 - Regular, occasional partners
 - Casual, anonymous partners
- Additionally ask about:
 - Any exchange of money/drugs for sex
 - Injection drug use
 - Intimate partner violence
 - Experiences with healthcare

CDC Recommended Indications for PrEP Use by Injection Drug Users

- 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 (also evaluate by MSM and heterosexual criteria)

US Public Health Service “Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2014”

Case 3

- 36 year old man with fever, chills, mild rash
- Reports condomless receptive anal sex 3 weeks ago at a sex club
- Interested in PrEP

Signs and symptoms of acute HIV

- Fever
- Rash
- Sore throat
- Headache
- Swollen glands
- Diarrhea



Source: www.etsu.edu

Truvada for PrEP and Resistance

Trial	Resistance Among Those Infected at Enrollment	Resistance Among Those Infected Later In The Study
iPrex	1 of 8 in the placebo arm 2 of 2 in the PrEP arm	0 of 64 in the placebo arm 0 of 36 in the PrEP arm
Partners PrEP	1 of 6 in the placebo arm 2 of 8 in the PrEP arm	0 of 52 in the placebo arm 0 of 30 in the PrEP arm
TDF2	1 of 2 in the placebo arm 1 of 1 in the PrEP arm	1 of 24 in the placebo arm 0 of 9 in the PrEP arm
TOTAL	1 of 16 in the placebo arm 5 of 11 in the PrEP arm	1 of 140 in the placebo arm 0 of 75 in the PrEP arm

7 with resistance: 5 of 7 with HIV before starting Truvada

Adapted from Ard. PrEP in the Real World

Clinical setting and team

- Routine primary care
 - Create PrEP friendly environment
 - Use CDC infographics
- PrEP champion
- Add tools into e-health system
 - Best practice advisories
 - Patient self-completed risk assessment
- Social worker or benefits expert

<http://www.cdc.gov/hiv/library/infographics.html>

<http://www.cdc.gov/hiv/prevention/research/prep/>

Typical Clinical Evaluation

- Baseline
 - 4th generation HIV Ab/Ag or HIV RNA testing
 - STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
 - Hepatitis B & C screening
 - HBV vaccine if negative
 - Kidney function testing
- Every 3 month follow-up
 - HIV testing
 - Pregnancy test for women who may become pregnant
 - STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
 - Kidney function testing (at 3 months then 6-mos.)
 - Bone scan not recommended

Prescribe Truvada

- Truvada 1 tab daily by mouth, #30, refills x 2
- Follow-up visit at 1 month to review dosing, adherence, side-effects
- Manage other interventions, vaccinations, etc.
- Risk-reduction counseling
 - How do you keep yourself at low risk from STIs?
 - Any substance use issues?
 - How does substance use impact sexual behavior?
 - Identify at least one concrete step to reduce risk

Medication Assistance

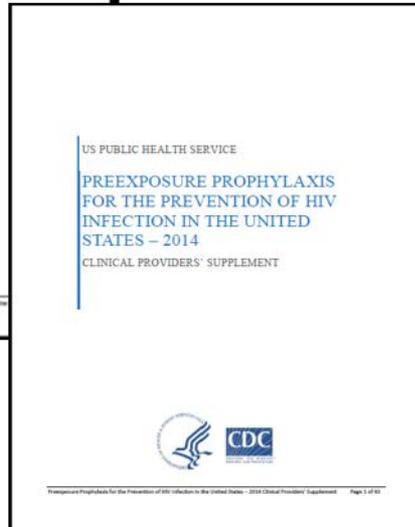
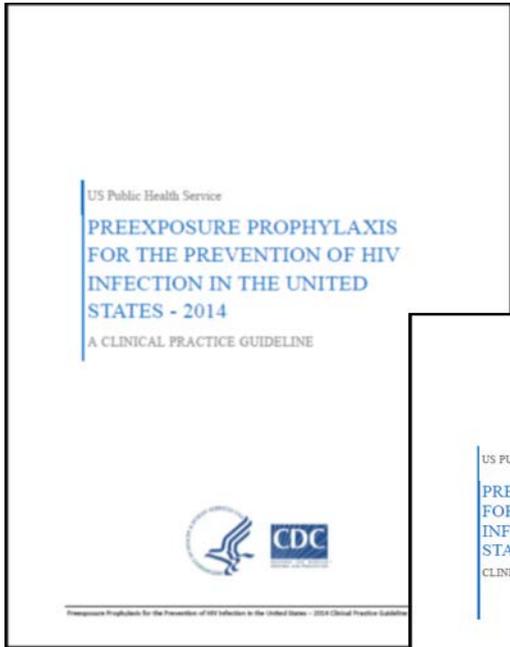
- Gilead will provide Truvada for PrEP at no cost for individuals who qualify for the assistance program (< 500% poverty level)
- Gilead will provide Co-Pay assistance for insured patients

Program Element	Truvada PrEP Medication Assistance Program
Eligibility Criteria	US resident, uninsured or no drug coverage, HIV-negative, low income
Drug Fulfillment	Product dispensed by Covance Specialty Pharmacy, labeled for individual patient use and shipped to prescriber (30 day supply); no card or voucher option
Recertification Period	6 months, with 90 day status check

Programmatic Support

CDC

Gilead



Checklist for Prescribers:
 Initiation of TRUVADA® for Pre-exposure Prophylaxis (PrEP)

Individual Label

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:

Laboratory 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 FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. Start TRUVADA for a PrEP indication in individuals with uninfected HIV-1 status or who are HIV-1 positive
- Confirmed HIV 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, serum glucose, and other 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 as reasons potential risks and benefits of continued use
- Confirmed that the uninfected individual of high-risk is not taking other HIV-1 medications or HIV medication
- Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

Consent/Follow-up

- Discussed known safety risks with use of TRUVADA for a PrEP indication
- Discussed the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening (at least every 3 months) while using TRUVADA for a PrEP indication to monitor HIV-1 negative status
- Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to the development of resistant HIV-1 variants
- Discussed the importance of adherence to daily dosing schedule
- Discussed that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention plan
- Discussed on protecting safe 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 (STI), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- Offered HIV vaccination as appropriate
- Provided education on when information about TRUVADA for a PrEP indication can be accessed
- Reviewed potential adverse reactions
- Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk

Truvada
 emtricitabine/tenofovir disoproxil fumarate

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

Individual Label

Instructions: Review form with an HIV-negative person who is about to start or is taking TRUVADA for a PrEP indication at each visit. File form in the person's medical record.

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 of high risk:

- Has partner(s) known to be HIV-1 infected, or
- Engage 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

GILEAD **Truvada® for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program**

Application to be used for TRUVADA (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) for PrEP only

Fax 1-855-330-5478 to begin enrollment CLEAR FORM

1 Applicant Information

Applicant Name: _____ ENGLISH SPANISH OTHER
 Applicant Language:

Address: _____
 City: _____ State: _____ Zip: _____ Phone #: _____

Social Security #: _____ Date of Birth: MM DD YYYY Gender: _____ Resides in U.S./U.S. territories: YES NO

Primary Contact: _____ Relationship: _____ Phone #: _____

Applicant Financial Information

Current Annual Household Income: _____ Number in Household (select one): 1 2 3 4 5 6
 Please include current documentation for all sources of income (e.g., tax returns, W-2, pay stubs, etc.)

Applicant is insured (Please fill out all the applicable insurance information below. Attach copy (front and back) of applicant insurance card)
 Applicant is uninsured (No health insurance through any public or private payor) (Complete "Additional Insurance Information" below)

Primary Payer Name: _____ Is this a Medicare Part D plan? YES NO
 Plan Name: _____ Payer Phone #: _____
 Subscriber Name: _____ Policy #: _____ Group #: _____

Check box if applicant has secondary insurance coverage and has insurance cards, if available.

Additional Insurance Information

	YES	NO
Has the applicant applied for Medicare Part D?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, date of application: _____		
If No, provide reason: _____		
Has the applicant applied for Medicaid?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, date of application: _____		

Not where prohibited by law. Applicants who are enrolled in health care or have coverage for prescription drugs under any other public program or have such coverage from any other third-party payer, are ineligible for the TRUVADA for PrEP Medication Assistance Program.

[Continue to page 2 >>](#)

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<http://www.cdc.gov/hiv/prevention/research/prep/>

<http://www.truvadapreprems.com/>



Online Resources

<http://www.cdc.gov/hiv/guidelines/preventing.html>

<http://www.projectinform.org/orderprepbooklets/>

http://www.thebody.com/index/treat/tenofovir_prevention.html

<http://prepfacts.org/>

Other issues



“PrEP is a party drug” Michael Weinstein, AHF



PrEP users fight back

Clinical Resources

- **Jeffrey D. Klausner, MD, MPH**
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