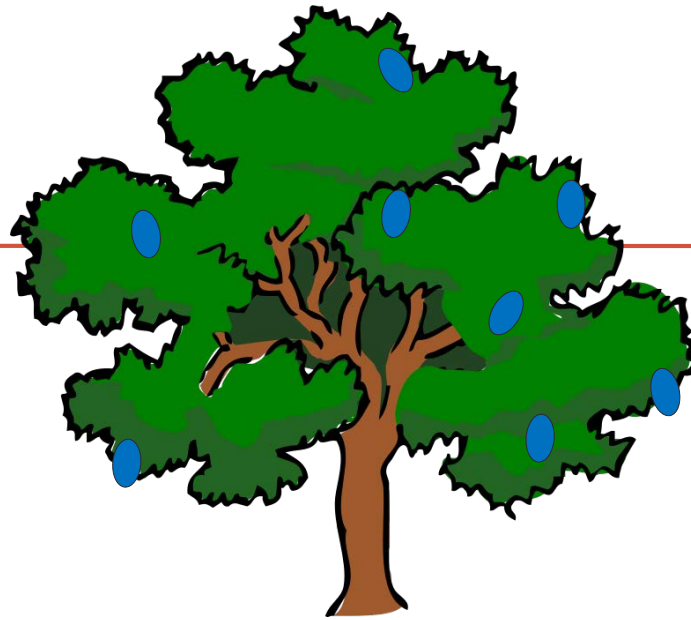


PREVENTION DOESN'T GROW ON TREES

THE REAL COST OF PREP



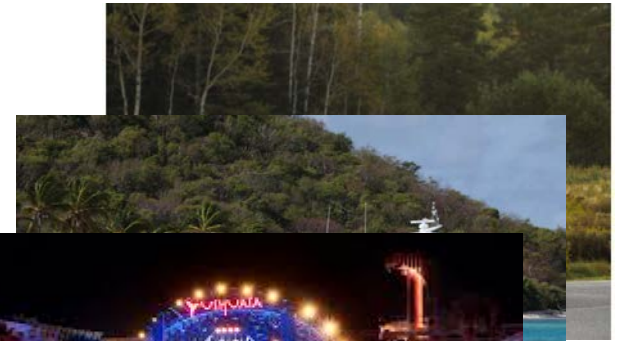
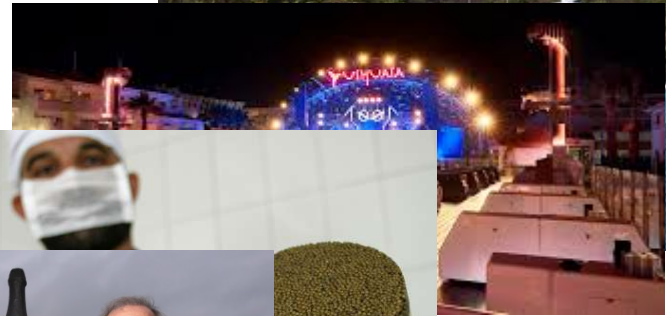
Sean Kelly, MD
Vanderbilt Division of Infectious Diseases

Objectives

- Understand the drug cost structure
- Review the different Truvada® cost assistance programs
- Review cost effectiveness studies of pre-exposure prophylaxis
- Discuss different patient scenarios

The Cost of Truvada®

- Out-of-pocket cost of TDF/FTC*
 - Per pill: \$67.03
 - Per month: \$1,876.84
 - Per year: \$24,465.95



*Average Wholesale Price

The Cost of Truvada®

- Cheaper by component?
 - Tenofovir disoproxil fumarate: \$40.53/day*
 - Emtricitabine: \$21.26/day*
- \$61.79/day
- \$1,730/month
- \$22,553.35/year

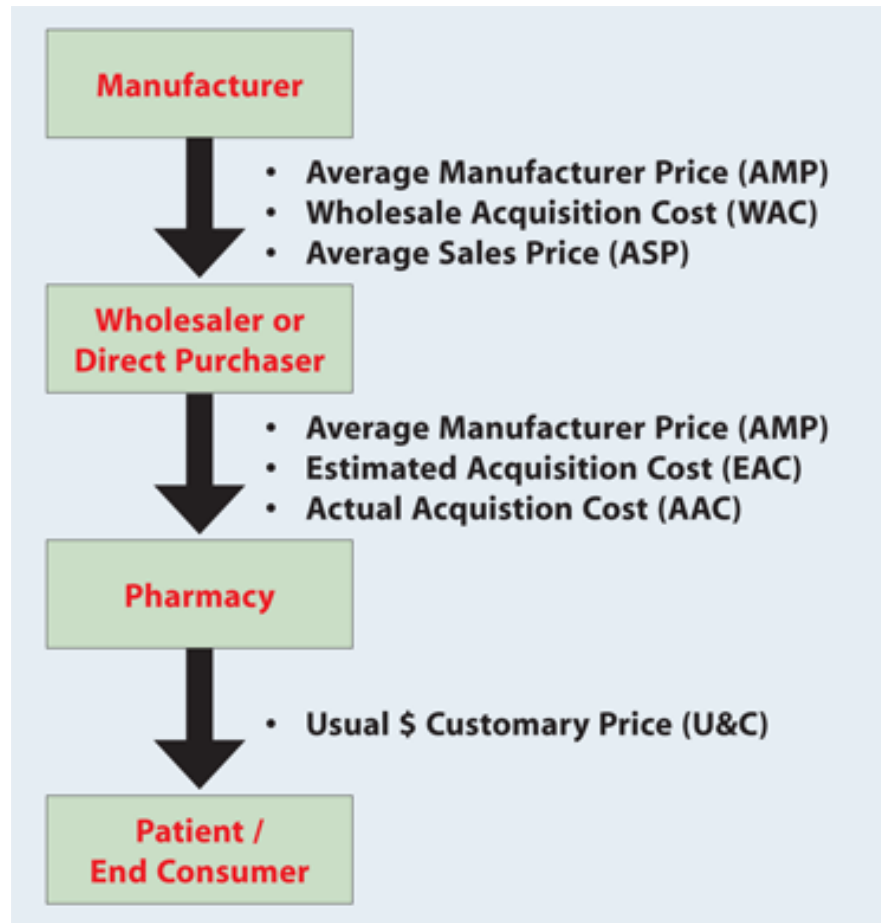
*Average Wholesale Price

Why so high?

- Research and development (such as DISCOVER trial)



The Different Costs



Manufacturer to wholesaler

- Wholesale Acquisition Cost (WAC)
 - Estimate of manufacturer's list price for a drug to wholesalers/direct drug purchasers, as defined by federal law
 - Does not include discounts or rebates
- Average Manufacturer Price (AMP)
 - Price a manufacturer charges purchasers, after discounts are taken into account, as defined by federal law
- Average Sales Price (ASP)
 - Cost from manufacturer to purchaser, inclusive of all discounts/rebates
 - Limited only to Medicare Part B-covered drugs

Wholesaler to pharmacy

- Average Wholesale Price (AWP)
 - Estimated price paid by pharmacies to purchase drug products from wholesalers
 - This is the “list price,” though not a true representation of actual market prices
 - Discounts/rebates not considered in this figure
- Estimated Acquisition Cost (EAC)
 - Estimated price state Medicaid programs use to reimburse pharmacies for the cost of the drug plus a dispensing fee
- Average Actual Cost (AAC)
 - Final cost paid by pharmacies to their wholesalers after all discounts have been deducted
 - Derived from audits of pharmacy invoices

Pharmacy to patient

- Usual and Customary Price (U&CP)
 - Cost to consumer from a retail pharmacy
 - Without the use of insurance



The Third Party


- Private, employer and federal insurance plans negotiate and contract for drug costs
- Insurance premiums (or other contributions) pay into this service
- The third party pays the pharmacy a portion
- The patient's makes up the remainder of the drug cost with the copayment



Truvada® Coverage

- Virtually all insurance plans cover TDF/FTC for the indication of HIV prevention
 - Variable copays
 - Prior authorization may be required
 - Though as low as 2% now require PAs
- Medicare/Medicaid cover TDF/FTC
- Flexible Spending Accounts (FSAs) can cover up to \$2,600 of out-of-pocket costs

Prior Authorization

 Drug Prior Authorization emtricitabine/tenofovir (TRUVADA)	
STEP 1: CLEARLY PRINT AND COMPLETE TO EXPEDITE PROCESSING	
Date: <u>02/28/2017</u>	Prescriber First & Last Name: <u>Sean Kelly</u>
Patient First & Last Name: _____	Prescriber NPI: <u>1932477171</u>
Patient Address: _____	Prescriber Address: <u>1211 21st Ave S Suite 102A Nashville TN 37232</u>
Patient ID: _____	Prescriber Phone: <u>615-936-1174</u>
Patient Date of Birth: _____	Prescriber Fax: <u>615-375-0666</u>
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) <input type="checkbox"/> Prescribed for the active treatment of HIV or HBV	
DIAGNOSIS B: Post-Exposure Prophylaxis (Approve for 1 Month) <input type="checkbox"/> 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) <input type="checkbox"/> 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 <input type="checkbox"/> Patient is \geq 18 years of age AND <input type="checkbox"/> Patient is HIV negative: Please provide date of last test: _____ AND <input type="checkbox"/> Prescriber has completed the REMS Prescriber Checklist: http://www.truvada-prep.com/Content/pdf/Checklist_for_Prescribers.pdf AND <input type="checkbox"/> Patient and prescriber have signed the REMS Agreement Form and it is saved in the patient's medical chart: http://www.truvada-prep.com/Content/pdf/Agreement_Form.pdf Please provide expected duration of treatment: _____	
DIAGNOSIS D: Pre-Exposure Prophylaxis (Continuing Coverage) (Approve for 3 Months) <input checked="" type="checkbox"/> Patient is Human Immunodeficiency Virus (HIV) negative Please provide date of last test: <u>12/30/2016</u>	
STEP 3: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-668-8551	
Prescriber Signature: <u>Sean Kelly, MD</u>	Date: <u>2-28-17</u>
If patient meets criteria, allow 2 business days for processing	

Financial Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
Updated: July 20, 2018

YES

(employer, private, insurance marketplace, COBRA, Medicare, Medicaid)

1

Gilead Advancing Access Co-pay Card

gileadcopay.com
877-505-6986

- \$7,200 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 process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at gileadcopay.com.

2

Patient Access Network Foundation

panapply.org
866-316-7263

- \$4,800 initial grant, up to \$8,000 max/year, re-apply
- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- 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)

tinyurl.com/PAFhelp,
or coays.org

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

FSA (flexible spending account)

Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.

If you're a resident, these state plans may also help if you're insured or uninsured:

- CALIFORNIA: tinyurl.com/CAprepAP
- COLORADO: tinyurl.com/COprepFAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAprepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31

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 (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

You can get insurance at other times for "qualifying life events" such as: pregnancy, loss/change of job, change in household size, change in income, recent move, change in citizenship.

FEB 1 – OCT 31

below 138% FPL / yr (< \$16,753)

above 138% FPL / yr (> \$16,753)

Check if you're eligible for your state Medicaid plan. (medicaid.org)

What's your income?

below

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

500% FPL (2018 FPL: \$12,140 taxable income + \$4,320 per dependent, higher FPL% in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)

~ only drug costs ~
tinyurl.com/FPLincomes

above

Retail cost of Truvada

NON-RESIDENT/
UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

Co-pay Assistance

1

Gilead Advancing Access Co-pay Card

gileadcopy.com
877-505-6986

- \$7,200 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 process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at gileadcopy.com.

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
Updated: July 20, 2018

NO

U.S. RESIDENT?

NON-RESIDENT/
UNDOCUMENTED?

What's the date?

NOV 1 – JAN 31

FEB 1 – OCT 31

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Check if you're eligible for your state Medicaid plan. (medicaid.org)

Check if you can get insurance through marketplace/employer.

IF NO

What's your income?

below

60,700

above

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www.truvada.com/truvada-patient-assistance

500% FPL (2018 FPL: \$12,140 taxable income + \$4,320 per dependent, higher FPL% in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)

Retail cost of Truvada

~ only drug costs ~
tinyurl.com/FPLIncome

3

Patient Advocate Foundation (PAF)
tinyurl.com/PAFhelp,
or coaays.org

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

Plans may be subject to funding shortfalls, which may limit enrollment.

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- COLORADO: tinyurl.com/COprepFAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAprepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

Copay Assistance

ADVANCING ACCESS[®] FINANCIAL SUPPORT INSURANCE SUPPORT

Get Started with
Gilead Advancing Access[®]
Program

Co-Pay Coupon Card

GILEAD
RxBIN: 610524
RxPCN: Loyalty
RxGRP: 50776283
ISSUER: (80840)
ID:

Not available for patients who are enrolled in government healthcare programs (e.g. Medicare Part D, Medicaid, VA, DSH, or ACA), and see [GILEADCOPIAY.com](#) for full terms and conditions.

Powered by
MCKESSON

Some information from your healthcare provider, so you may want to fill it out with them. [Download](#) the [Advancing Access Enrollment Form](#) or [Enroll Online](#)

Gilead Advancing Access Program

- \$7,200/calendar year benefit
 - Increased from \$3,600 to \$4,200 in January 2018
 - Increased from \$4,200 to \$7,200 in September 2018
- No income limitation
- Federal beneficiaries excluded
- Usually goes toward deductible
 - Beware of copay accumulator programs
 - Manufacturer copay assistance will no longer count toward deductible

Copay Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
Updated: July 20, 2018

Patient Access Network Foundation

panapply.org
 866-316-7263

- \$4,800 initial grant, up to \$8,000 max/year, re-apply
- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

1 Gilead Advancing Co-pay Card

gileadcopay.com
877-505-6988

- \$7,200 max/calendar year
- No income restriction
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as required
- US resident
- Not available for persons on Medicaid, Medicare, Veterans Affairs, or state/federal prescription drug programs

If pharmacy is unable to accept Gilead's Co-pay Card, you may use the pharmacy receipt number on back of card to request reimbursement for all restrictions apply: terms and conditions at gileadcopay.com

3 Patient Advocate Foundation (PAF)

patientadvocate.org/PAFhelpdays.org

Apply for assistance every year, re-apply every 100% FPL (\$48,560) of living index

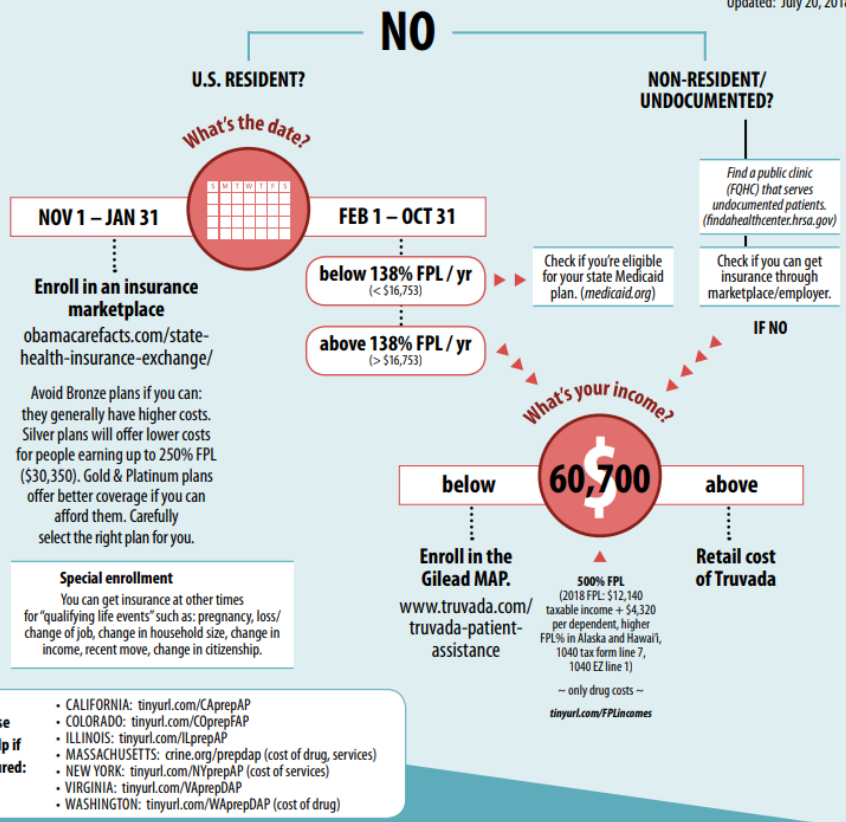
Eligible income (1040 EZ line 1) required (as listed above)

Covers only residence (utility bills) and services available to medical cost (532-5274)

Shortfalls, see website

FSA (flexible spending account)

Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.



Copay Assistance



Copay Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
Updated: July 20, 2018

YES

(employer, private, insurance marketplace, etc.)

1

Gilead Advancing Access Co-pay Card
gileadcopay.com
877-505-6986

- \$7,200 max/calendar year
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- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
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- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

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2

Patient Advocate Foundation (PAF) Network Four
panapply.com
866-316-7900

- \$4,800 initial grant, \$8,000 max/year, re-apply annually
- Income <500% FPL
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill Foundation directly

These programs are available to patients who are not covered by Medicaid, Medicare, VA or other state/federal prescription drug programs.

FSA (flexible spending account)
Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.

3

Patient Advocate Foundation (PAF)
tinyurl.com/PAFhelp, or coays.org

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31

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 (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

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- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

FEB 1 – OCT 31

below 138% FPL / yr (< \$16,753)

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above 138% FPL / yr (> \$16,753)

What's your income?

below

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

60,700

500% FPL (2018 FPL: \$12,140 taxable income + \$4,320 per dependent, higher FPL% in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)

— only drug costs —
tinyurl.com/FPLincomes

above

Retail cost of Truvada

Copay Assistance



Providing Critical Financial Support for Patients Nationwide Since 2004

[HOME](#) | [HOW WE HELP](#) | [DISEASES](#) | [PROGRAM & MEDIA UPDATES](#) | [FREQUENTLY ASKED QUESTIONS](#) | [OUR PATIENTS](#) | [ABOUT US](#) | [DONATE](#)

[Online Application](#)

ELIGIBILITY REQUIREMENTS

Do I qualify for financial assistance?

HOW TO APPLY ONLINE

[Patient](#), [Provider](#) and [Pharmacy Instructions](#)

PATIENT TESTIMONIALS

What our patients are saying about CPR...



WELCOME TO PATIENT ADVOCATE FOUNDATION'S CO-PAY RELIEF

What is the Patient Advocate Foundation Co-Pay Relief Program?

PAF Co-Pay Relief (CPR) provides direct financial assistance to qualified patients, assisting them with prescription drug co-payments their insurance requires relative to their diagnosis. CPR call counselors work directly with the patient as well as with the provider of care to obtain necessary medical, insurance and income information to advance the application in an expeditious manner. Upon approval, payments are made.

COMPANY NEWS ANNOUNCEMENTS

Email Address *

First Name *

Last Name *

Send me messages about these PAF topics

PAF News, Patient Resources & Disease

Medication Access Program

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
Updated: July 20, 2018

YES

(employer, private, insurance marketplace, COBRA, Medicare, Medicaid)

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2

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- NEW YORK: tinyurl.com/NYprepAP (cost of services)
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- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

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U.S. RESIDENT?

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FEB 1 – OCT 31

below 138% FPL / yr
(< \$16,753)

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above 138% FPL / yr
(> \$16,753)

NON-RESIDENT/
UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

What's your income?

below

60,700

above

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

Retail cost of Truvada

100% FPL: \$12,140
95% FPL: \$12,140 + \$4,320
80% FPL: \$12,140 + \$4,320 + \$4,320
70% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320
60% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320
50% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320
40% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320
30% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320
20% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320
10% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320
0% FPL: \$12,140 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320 + \$4,320

Medication Assistance Program

The screenshot displays the Gilead Advancing Access website. At the top, the navigation bar includes the Gilead logo, "ADVANCING ACCESS", and menu items for "FINANCIAL SUPPORT" and "INSURANCE SUPPORT". A large red banner features the text "INSURANCE SUPPORT" and three links: "Help with Coverage & Benefits", "Help When Insurance & Coverage Changes", and "Understanding Insurance". Below the banner, three program highlights are shown: "The Advancing Access CO-PAY COUPON PROGRAM", "The Advancing Access PATIENT SUPPORT PROGRAM", and "Advancing Access OVERVIEW". A red arrow points from the main title to the "INSURANCE SUPPORT" banner, and another red arrow points from the "PATIENT SUPPORT PROGRAM" link to the "INSURANCE SUPPORT" banner.

ADVANCING ACCESS

FINANCIAL SUPPORT INSURANCE SUPPORT

INSURANCE SUPPORT

- Help with Coverage & Benefits >
- Help When Insurance & Coverage Changes >
- Understanding Insurance >

The Advancing Access CO-PAY COUPON PROGRAM
Helping you save on your Gilead prescription co-pay. [Get Started](#)

The Advancing Access PATIENT SUPPORT PROGRAM
Financial and coverage support for your Gilead medication. Call 1-800-226-2000, [download the Enrollment Form](#), or [enroll online](#) to get started.

Advancing Access OVERVIEW

GILEAD Terms of Use | Privacy Policy | Contact Us | Site Map

ADVANCING ACCESS, GILEAD, and the GILEAD Logo are trademarks of Gilead Sciences, Inc.

Medication Assistance Program

ADVANCING ACCESS[®]

1. REQUESTED PATIENT SUPPORT (REQUIRED)

Benefits Investigation Prior Authorization and
 Patient Assistance Program (PAP) or Medication Assistance Program (MAP) E

2. GILEAD MEDICATION PRESCRIBED (REQUIRED)

Product Name: _____

If requesting TRUVADA[®], please indicate for: Treatment PrEP

3. PATIENT INFORMATION (REQUIRED)

First Name: _____ Last Name: _____
 Address: _____ Apt./Unit # _____
 State: _____ Zip Code: _____
 Email: _____
 Alternate Contact Name: _____

CONTACT AUTHORIZATION

I authorize Advancing Access to leave a detailed message, including the name of m

4. INSURANCE INFORMATION (REQUIRED) **PL**

Patient is insured (Please fill out all of the applicable insurance information below. Attach copy – front and back – of patient card.)

Primary Insurance: _____ Is _____
 Plan name: _____ In _____
 Subscriber Name: _____ Policy Holder Name: _____
 Policy #: _____ Group #: _____

Check box if patient has secondary insurance coverage and fax a copy of ins

5. PRESCRIBER INFORMATION (REQUIRED)

Prescriber Name: _____ Fa _____
 Address: _____ Cr _____
 State: _____ Zip Code: _____ Cr _____
 Phone #: _____ Fa _____
 Tax ID #: _____ St _____

6. DIAGNOSIS/MEDICAL INFORMATION

Diagnosis (Please include ICD code): _____

7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY

By signing this form, I certify that I am prescribing Gilead medication for the patient identified in patient and that it will be used as directed. I certify that I will be supervising the patient's treatment of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed Program ("PAP/MAP") from any government program or third-party insurer.

If prescribing TRUVADA for PrEP[®], I certify that the applicant has been tested for HIV infection at applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued I certify that I have received the appropriate written authorization from the patient, in accordance health information privacy laws, and any other applicable requirements, in order to release the p the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking support, and referral support as needed; 4) facilitating the provision of the patient's prescription in patient's prescription medication or to evaluate the effectiveness of the Advancing Access Progra

PRESCRIBER SIGNATURE (REQUIRED):

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ENROLLMENT FORM PAGE 1 OF 3
 PHONE: 1-800-226-2056 FAX: 1-800-216-6857

ADVANCING ACCESS ENROLLMENT FORM PHONE: 1-800-226-2056 FAX: 1-800-216-6857

PATIENT NAME: _____ DA _____

8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQU

I understand that I must complete this enrollment form before I can receive assista Advancing Access ("Program") and the Patient Assistance Program/Medication Assi of this process, Gilead and its agents and contractors (collectively, "Gilead") will nee my personal and medical information as described below. I hereby authorize my he disclose my personal and medical information as described below to Gilead in con PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use an with the authorization.

Information to Be Disclosed: Personal health information ("PHI"), including informa name, mailing address, financial information, and insurance information), my past (including information about my HIV-related status or treatment with this prescrip condition), and all information provided on this enrollment form.

Persons Authorized to Disclose My Information: My healthcare providers, including medication, and any health plans or programs that provide me healthcare benefits providers may receive remuneration for disclosing my PHI pursuant to this authori

Persons to Which My Information May Be Disclosed: Gilead, including the third par administration of the Program and the PAP/MAP.

Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be ma disclose the PHI for purposes of: 1) completing the enrollment process and verifyin my eligibility for benefits from my health plan or other programs; 3) providing fina support, and communicating with my healthcare providers, including, but not limit prescription medication to me; 4) contacting me to evaluate the effectiveness of the Gilead's internal business purposes, including quality control and support enhanc information, offers, and educational materials related to my treatment and/or my p customer relationship marketing program (this use of my personal information is o the signatures below, I may opt in).

I understand that once my PHI has been disclosed hereunder, federal privacy law m I understand further that I may refuse to sign this authorization and that if I refuse, ability to obtain treatment from my healthcare providers will not change, but I will r by Program and/or the PAP/MAP. I also understand that I may cancel this authorizat writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gil to obtain, use or disclose my PHI after the cancellation date, but the cancellation w PHI that have already been made pursuant to this authorization before the cancella signed authorization, which expires the earlier of two (2) years from the date it is sig under the laws of the state in which I reside.

By checking this box, I agree to receive marketing information, offers and educational materials relat prescription medication, including the customer relationship marketing program.

SIGNATURE OF PATIENT or PATIENT'S REPRESENTATIVE (REQUIRED):

Patient Representative's Name (if signing for the patient):

Patient Representative's Relationship to Patient:

FAX COMPLETED FORM TO ADVANCING ACCESS AT

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ADVANCING ACCESS ENROLLMENT FORM PHONE: 1-800-226-2056 FAX: 1-800-216-6857

PATIENT NAME: _____ DATE OF BIRTH: _____

9. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPLYING FOR THE PATIENT ASSISTANCE PROGRAM/MEDICATION ASSISTANCE PROGRAM (PAP/MAP)

Current Annual Household Income: \$ _____

Number of People in Household supported by above income: 1 2 3 4 5 6 Other: _____

Please submit current documentation for all sources of income (eg, tax returns, W2, last 2 pay stubs, etc.).
 If there is no household income, indicate how the patient/household is being supported:

ADDITIONAL INSURANCE INFORMATION

Social Security Number: _____

Has the patient applied for ADAP? Yes No If Yes, date of application: _____

Has the patient applied for Medicaid? Yes No If Yes, date of application: _____

Is the patient eligible for Medicaid? Yes No If No, state reason: _____

Is the patient eligible for VA benefits? Yes No If Yes, has the patient tried to obtain the medication through the VA? Yes No

Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)? Yes No If Yes, date of application: _____

Is the patient eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)? Yes No If No, state reason: _____

APPLICANT DECLARATIONS AND AUTHORIZATIONS (REQUIRED ONLY IF APPLYING FOR THE PAP/MAP)

I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if Advancing Access becomes aware of any false or inaccurate information or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. If I receive free product through the PAP/MAP, I certify that I will not seek reimbursement or credit for this medication from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this medication or any cost for items associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that the PAP/MAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize the PAP/MAP and its administrator to forward my prescription to a dispensing pharmacy on my behalf. I authorize Gilead and its third party administrator to use the information provided on this form to obtain a personal credit report about me to verify the information on this form and determine my eligibility for the PAP/MAP.

SIGNATURE OF PATIENT/PATIENT REPRESENTATIVE: _____ DATE: _____
 (REQUIRED ONLY IF APPLYING FOR PAP/MAP)

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

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State Plans

- Illinois - IDPH PrEP Assistance Program
 - PrEP Navigation, funding for cost assistance through IDPH
- Massachusetts - Massachusetts Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
 - Assistance for copays, co-insurance, full cost of Truvada ®
 - Limited to <500% FPL
- Washington - Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
 - PrEP Navigation, assistance for medication and cost of labs/visits
 - No income limitation
- New York - Pre-exposure Prophylaxis Assistance Program (PrEP-AP)
 - Assistance for cost of labs and provider visits
 - Enrollment criteria based on AIDS Drug Assistance Program (ADAP)
- California - PrEP Assistance Program (PrEP-AP)
 - Launched early 2018
 - Assistance for cost of labs and provider visits
 - Limited to <500% FPL

Advice to patients

- Find out your deductible
- Find out your Truvada® copay
- Find out your estimated costs of visits and labs
- If you need an insurance plan from the marketplace, avoid Bronze Plans due to high out-of-pocket expenses
- Use Flexible Spending Account to offset any out-of-pocket expenses

Vanderbilt PrEP Clinic

- Sample: N=69
- Insurance plans: Cigna, Aetna, TennCare
- Specialty Pharmacies: Navitus, CVS Caremark, OptumRx, Express Scripts
- Copay range: \$30 - \$400/month

Vanderbilt PrEP Clinic

- Patients paying any out-of-pocket cost: 11
 - TennCare (\$3 copay): 3
 - Qualified for assistance through foundation: 3
- Annual out-of-pocket costs (N=5): \$220 - \$2400
 - Copay assistance goes toward deductible/out-of-pocket max until exhausted
 - Remainder of deductible paid throughout the remainder of the year

Other cost considerations

Encounter	To do
Month 0	<ul style="list-style-type: none">• Screen for HIV• Confirm HBV and HCV status• Check serum creatinine• Screen for STIs
Month 3	<ul style="list-style-type: none">• Screen for HIV• Check serum creatinine
Month 6	<ul style="list-style-type: none">• Screen for HIV• Screen for STIs
Month 9	<ul style="list-style-type: none">• Screen for HIV• Check serum creatinine
Month 12	<ul style="list-style-type: none">• Screen for HIV• Screen for STIs

Labs:

- HIV screen: 5
- Serum creatinine: 3
- STI screen: 3
- HBV screen: 1
- HCV screen: 1

Clinic visits: 5

Other:

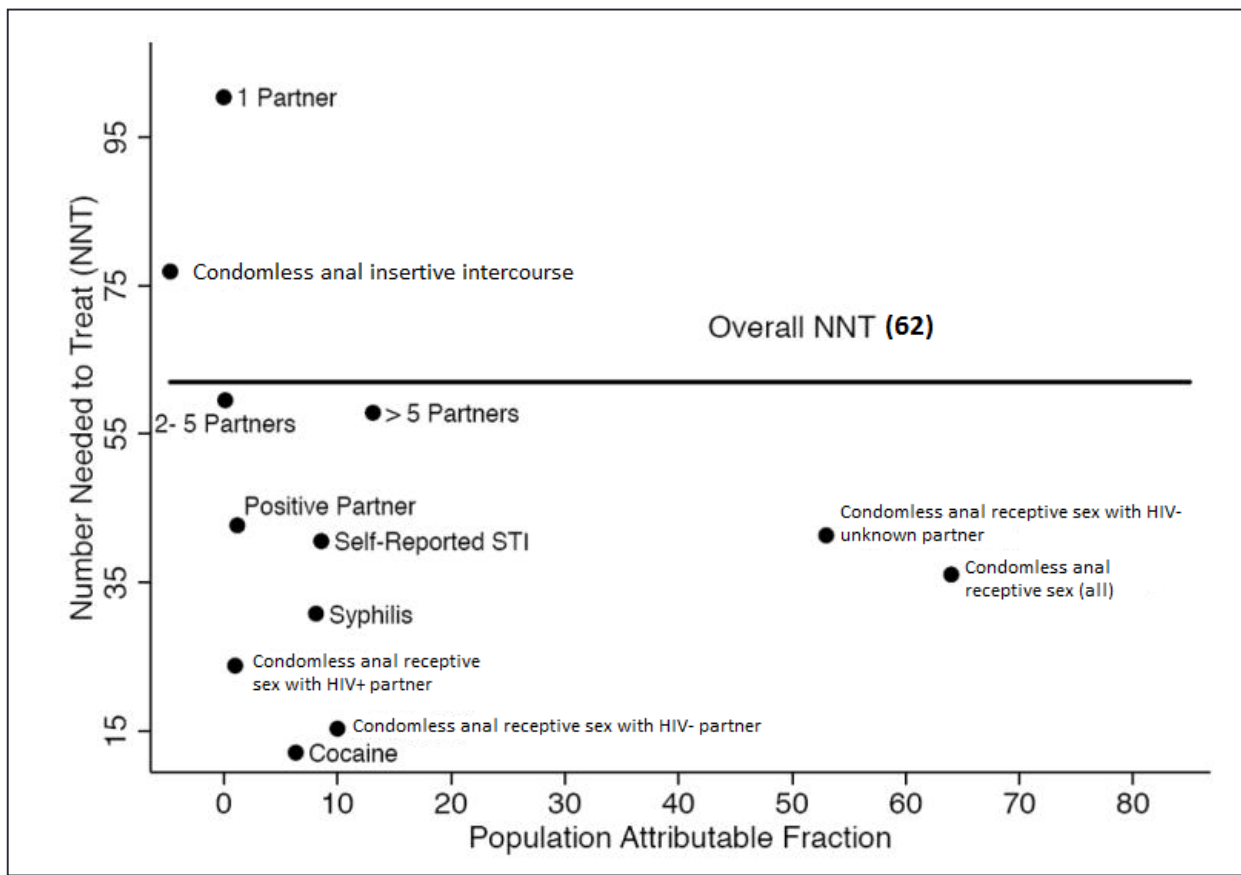
HBV vaccination
STI Treatment

Cost effectiveness of PrEP

Number needed to treat

- Number needed to treat
 - Inverse of absolute risk reduction
 - Varies depending on population
 - Key factors are HIV prevalence, acquisition risk factor, and efficacy of PrEP
 - In reality, these factors vary within a single population

Number needed to treat



Overall, NNT = 62

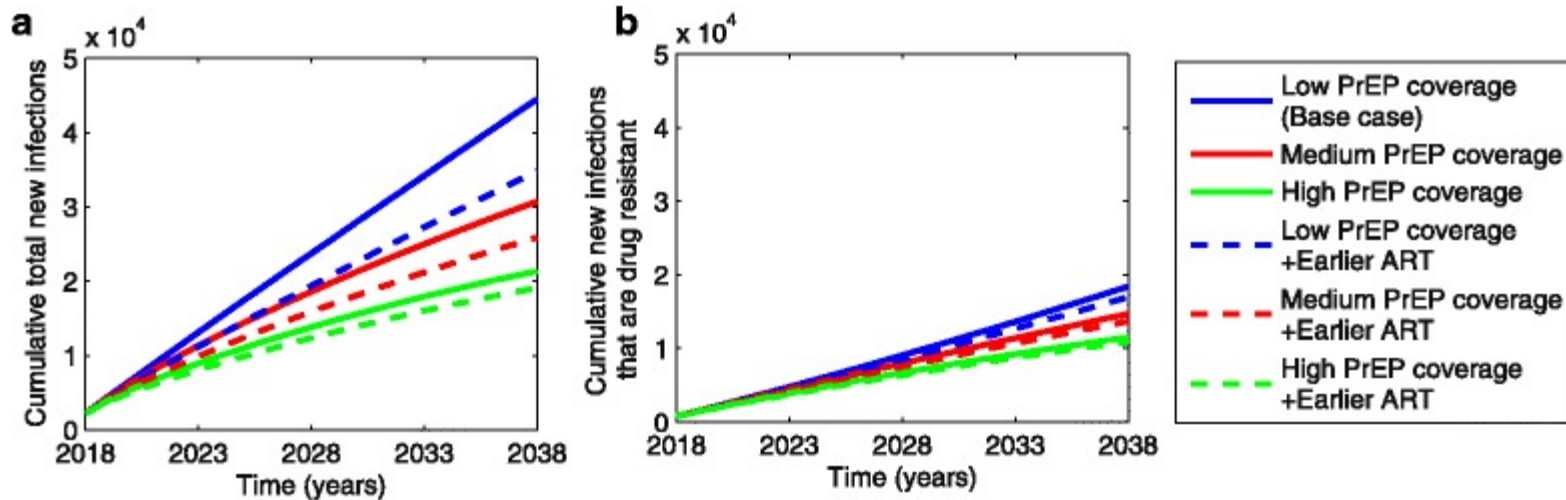
Lower NNT:

- Condomless anal receptive sex
- STIs
- Cocaine use

Cost effectiveness of PrEP

- Incremental cost effective ratio (ICER)
 - The difference in cost between two possible interventions, divided by the difference in their effect
 - Equivalent to the cost per quality-adjusted life year (QALY)
 - Cost effectiveness depends on the population
 - Very cost effective strategy = $ICER < \text{per capita GDP}$
 - Cost effective strategy = $ICER < 3x \text{ per capita GDP}$

Cost effectiveness of PrEP



Cost effectiveness of PrEP in reducing HIV depends on:

- Extent of PrEP coverage
- Other factors that reduce HIV

Cost effectiveness of PrEP

- In San Francisco, expanding PrEP is cost-effective, *especially when combined with early ART*
 - PrEP for 80% of high-risk individuals would reduce new infections 52% over 20 years
 - Cost of \$132,520 per QALY gained
 - Earlier ART would reduce new infections by 22% over 20 years
 - Cost of \$4745 per QALY gained
 - PrEP for 80% + earlier ART would reduce new infections by 57% over 20 years
 - Cost of \$115,320 per QALY gained

Per capita GDP of San Francisco = \$81,347
Per capita GDP in San Francisco x 3 = \$244,041

Cost effectiveness of PrEP

- Cost per QALY gained varies by city and population
 - High-risk MSM in NYC: \$31,970
 - High-risk MSM in Los Angeles: \$27,863 – \$37,181
 - High-risk MSM in USA: \$52,443
 - All MSM in USA: \$172,091 – \$216,480

Per capita GDP of USA: \$57,466.79

Cost effectiveness of PrEP

- To make PrEP cost-effective:
 - Target those at highest HIV risk for intervention
 - Combine with other HIV-reduction efforts
 - Lower the cost of PrEP?

Patient scenarios

Case 1

- 29yoM presenting to discuss initiation of TDF/FTC for HIV risk reduction. He is MSM, has anal insertive and receptive sex with inconsistent condom use, and has a history of chlamydia. He is enrolled in an ACA Marketplace Bronze Plan. He is self-employed with an annual income for >\$70,000.

Case 1

- He contacted his insurance company and discovered his monthly copay for Truvada is \$500.

Case 1

Which assistance option will be most helpful in making Truvada[®] affordable?

- A. Patient Advocate Foundation (PAF)
- B. Gilead Advancing Access Program
- C. Gilead Medication Access Program
- D. Patient Access Network Foundation
- E. None, he can afford it

Case 1

Which assistance option will be most helpful in making Truvada affordable?

- A. Patient Advocate Foundation (PAF)
- B. **Gilead Advancing Access Program**
- C. Gilead Medication Access Program
- D. Patient Access Network Foundation
- E. None, he can afford it

This is the Gilead copay assistance program

- No income limitations
- Up to \$7,200 benefit per calendar year
- Federal beneficiaries excluded

Case 1

- Annual copay cost = $\$500 \times 12 = \6000
- Copay cost is less than Gilead Advancing Access \$7200 annual benefit
- Out-of-pocket medication cost = \$0

Case 2

- 65yoM who has been taking TDF/FTC for the past year. He is married to a woman who is HIV+, engaged in care and reportedly undetectable. He recently enrolled in Medicare, but did not enroll in Part D. He therefore has no coverage. He makes \$30,000 annually.

Case 2

What can be done?

- A. Explore enrollment in Medicare Part D
- B. Gilead Medication Access Program
- C. Explore private foundations (PAN, PAF)
- D. All of the above

Case 2

What can be done?

- A. Explore enrollment in Medicare Part D
- B. Gilead Medication Access Program
- C. Explore private foundations (PAN, PAF)
- D. **All of the above**

- Why didn't he enroll in Medicare Part D?
- If enrolled in Part D, PAN/PAF could offer copay assistance (but PAN not currently accepting applications)
- His most reliable immediate option is Gilead MAP

Case 3

- 41yoM is taking TDF/FTC and pays \$0 for medication thanks to the Advancing Access Program. He states he recently received a bill for \$800 following administration of ceftriaxone for gonorrhea diagnosed at his last visit. He now declines any STI testing. He reports 11 partners over the past 3 months with inconsistent condom use.

Case 3

What would you recommend?

- A. Respect patient's autonomy and stop STI testing
- B. Test for STIs only every 6 months
- C. Discharge patient from your clinic as you cannot provide complete PrEP services
- D. Recommend STI testing at Health Department or FQHC

Case 3

What would you recommend?

- A. Respect patient's autonomy and stop STI testing
 - B. Test for STIs only every 6 months
 - C. Discharge patient from your clinic as you cannot provide complete PrEP services
 - D. **Recommend STI testing at Health Department or FQHC**
-
- Always advise patient to check with their insurance before ordering tests, scheduling visits, or administering medications.
 - If high costs are anticipated, there may be alternative sites that offer these services at lower costs.

Case 4

- You work at a large academic medical center. One of the partners of one of your HIV+ patients is interested in starting PrEP. He 34yoM, MSM, undocumented, uninsured and states cost is a major barrier for all of his healthcare. He recently received treatment for gonorrhea at an affordable local community health center.

Case 4

What is his best option?

- A. Schedule him in your clinic and enroll him in the Gilead Medication Access Program
- B. Recommend he discuss PrEP with his prior provider
- C. Discuss enrolling him in Ryan White
- D. Combine multiple different cost assistance programs

Case 4

What is his best option?

- A. Schedule him in your clinic and enroll him in the Gilead Medication Access Program
 - B. **Recommend he discuss PrEP with his recent provider**
 - C. Discuss enrolling him in Ryan White
 - D. Combine multiple different cost assistance programs
- This patient represents a significant high-risk group with low PrEP accessibility
 - Ryan White does not fund care for HIV-negative patients
 - He will need not only medication assistance, but assistance for labs and visits
 - FQHCs may have affordably discounted labs and visits. This, in combination with Gilead MAP, may make PrEP affordable
 - Could also investigate state funding, if available

Thank you!

Questions?