

PRE-EXPOSURE PROPHYLAXIS FOR HIV

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Objectives

- Background of PrEP
- Importance of PrEP in the Southeast
- Provider and patient barriers to PrEP
- PrEP eligibility
- PrEP prescribing
 - Counseling
 - Adverse effects
 - Lab monitoring





Secondary Objectives

Increase your confidence in providing PrEP! Provide PrEP!







What is 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 FDAapproved for this purpose







- Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg
- Developed by Gilead and marketed as Truvada®
- 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 June 2017
 - Became available September 2020



TAF/FTC (Descovy®)



- Similar to TDF/FTC
 - Truvada® = tenofovir disoproxil fumarate (TDF) + emtricitabine
 - Descovy® = tenofovir alafenamide (TAF) + emtricitabine
- Approved for PrEP October 2, 2019 for non-vaginal sex
- TAF achieves high intracellular concentrations, but lower (>10-fold) plasma and tissue concentrations than TDF
 - Lower risk of BMD loss and reduced creatinine clearance
 - Can be used in chronic kidney disease (CrCl >30 mL/min)



LA cabotegravir

- Long-active injectable
 - Optional oral lead-in
 - 2 doses 1 month apart, then every 2 months
 - Consecutive doses can be given 7 days before or after target date
- Approved 12/20/21
- Demonstrated superiority to TDF/FTC
- Injection site reactions are common



https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Inf ormation/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF

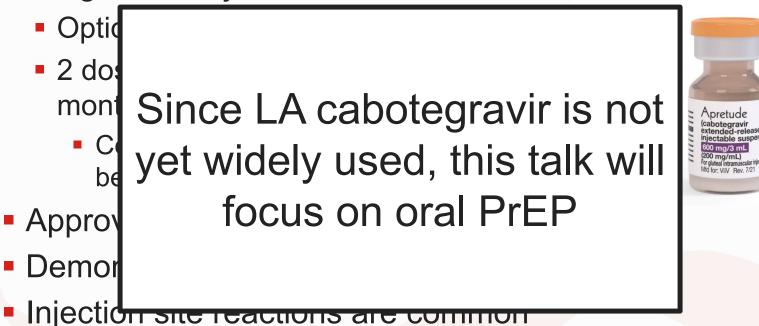


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LA cabotegravir

Long-active injectable



https://gskpro.com/content/dam/global/hcpportal/en US/Prescribing Inf ormation/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF

Apretude

600 mg/3 ml 200 mg/mL) gluteal intramuscu Ifd for: ViiV Rev. 7/21





TDF/FTC (TRUVADA®)		TAF/FTC (DESCOVY®)	
Pros	Cons	Pros	Cons
More data on efficacy, PK, dosing strategies…	Low risk of renal dysfunction	Lower risk of renal dysfunction	Fewer data, less experience
More experience	Reversible bone mineral density loss	Lower risk of bone mineral density loss	Can't be used for vaginal sex yet
Covered by all insurance	Larger pill size	Smaller pill size	Less insurance coverage
Can be used for vaginal and anal sex	Can't be used if eGFR <60	Faster time to therapeutic level	No data on 2-1-1 dosing
More brand recognition		Can be used if eGFR >30	Weight gain?
Generic available			Not cost effective



Walensky RP, Horn T, McCann NC, Freedberg KA, Paltiel AD. Comparative Pricing of Branded Tenofovir Alafenamide-Emtricitabine Relative to Generic Tenofovir Disoproxil Fumarate-Emtricitabine for HIV Preexposure Prophylaxis: A Cost-Effectiveness Analysis. Ann Intern Med. 2020;172(9):583-590. doi:10.7326/M19-3478

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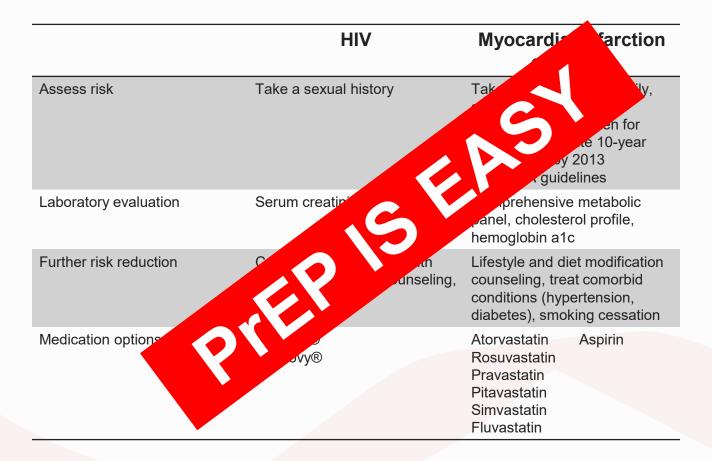
Primary Prevention

	HIV	Myocardial infarction or Stroke	
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	Condom use, sexual health and substance use counseling, STI screening	Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation	
Medication options	Truvada® Descovy®	Atorvastatin Aspirin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin	





Primary Prevention





PrEP is a PROGRAM

- Not only HIV prevention
- Involves comprehensive sexual healthcare
 - Screening and treatment for STIs
 - Hepatitis A and B vaccination
 - Counseling on STI prevention strategies







STIs Facilitate HIV Transmission

- Disruption of mucosal integrity
- Increase HIV target cells in genital tract due to immune reaction to infection
- STIs promote HIV shedding in the genital tract

Presence of ulcerative STI increases likelihood of HIV acquisition up to 5-fold!

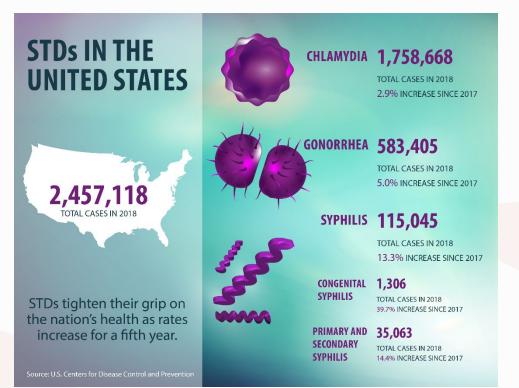
https://www.cdc.gov/std/hiv/stds-and-hiv-fact-sheet-press.pdf





Be afraid!

- PrEP does NOT protect against bacterial and other STIs
- These are at record highs!







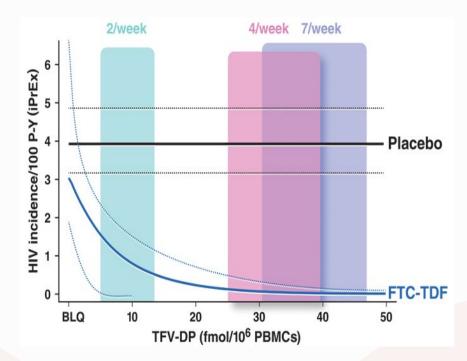
PrEP efficacy studies summary

Study	Population	Dosing	Risk Reduction	
iPrEX	MSM	Daily	44% (92% with ideal adherence)	
TDF2	Heterosexual men and women	Daily	62.2% (100% in open-label extension with regular follow- up)	
Partners	Sero-discordant heterosexual couples	Daily	75% (90% with ideal adherence)	
Bangkok Tenofovir Study Group	Intravenous drug users	Daily	48.9% (74% with ideal adherence)	
IPERGAY	MSM	On-demand	86%	





Dosing matters



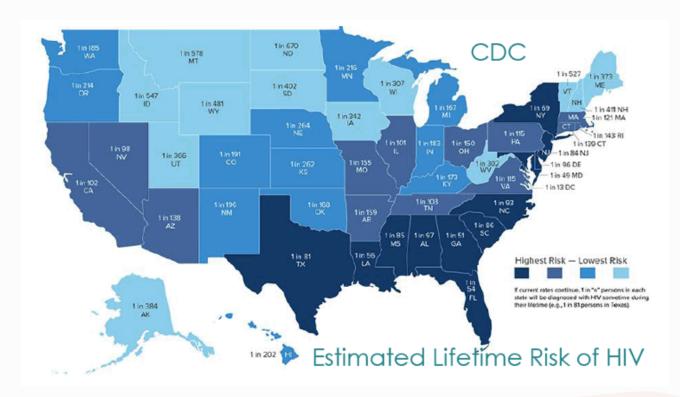
- Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict:
 - 76% risk reduction with 2 doses/week
 - **96%** with 4 doses/week
 - 99% with 7 doses/week.





Why PrEP Matters



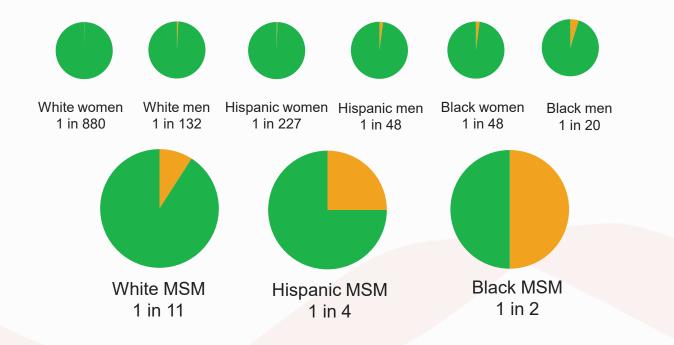


The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.





HIV Risk by Race/Ethnicity and MSM



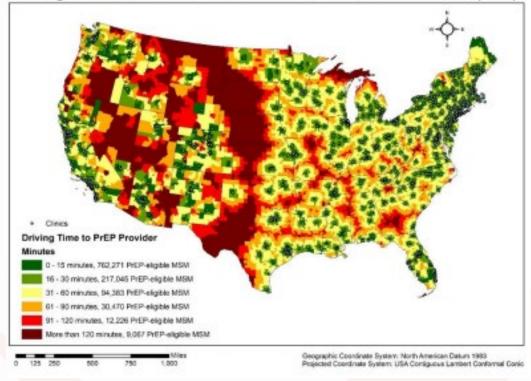






PrEP Deserts

Driving Time to Nearest PrEP Provider for men who have sex with men (MSM)



- 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.

Weiss K, et al. Access to PrEP clinics among US MSM: documenting PrEP deserts. Conference on Retroviruses and Opportunistic Infections, Abstract 1006; March 4–7, 2018, Boston, Massachusetts





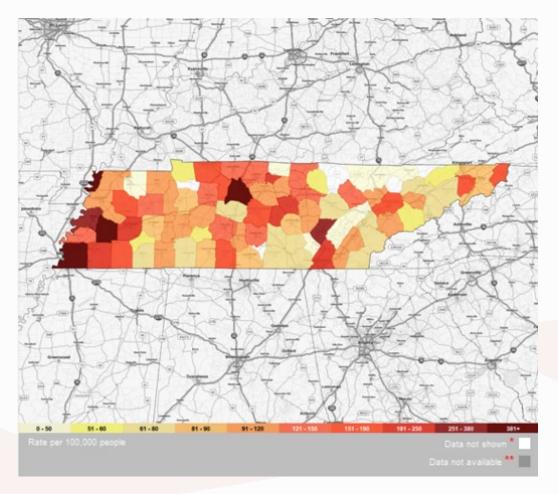






Tennessee

HIV risk and location of PrEP providers



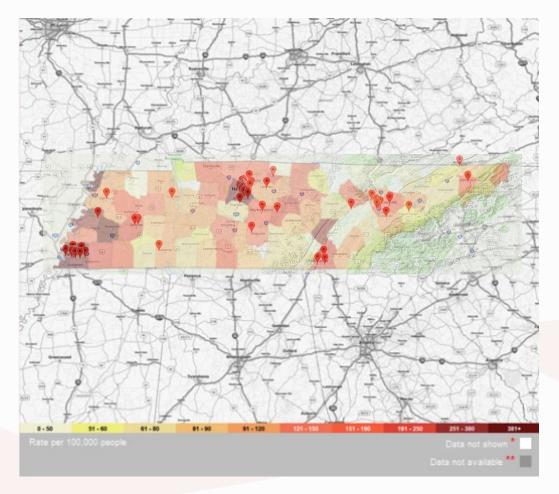


<u>https://aidsvu.org/state/tennessee/</u> https://getpreptn.com/get-pr<mark>ep/#map_top</mark>



Tennessee

HIV risk and location of PrEP providers





<u>https://aidsvu.org/state/tennessee/</u> https://getpreptn.com/get-pr<mark>ep/#map_top</mark>



Barriers to PrEP





PrEP sounds amazing!

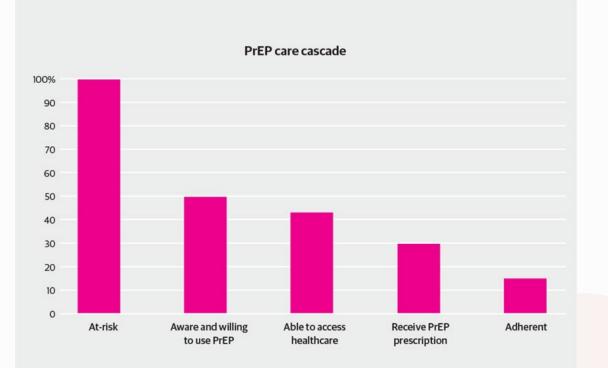
So why aren't we using it?







PrEP barriers





https://www.aidsmap.com. Sept 9, 2016 [Accessed April 9, 2018]



Stigma

A preventative measure against the consequences of sexual activity

... condones sexual activity

... promotes sexual activity

... causes sexual activity







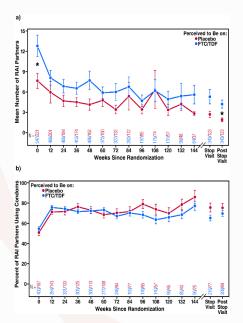
Sexual risk compensation

- PrEP users will engage in higher risk sex than they previously had.
- This increased unsafe sex will undermine prevention efforts.
- Higher rates of bacterial STIs diagnosed among PrEP users may falsely support this.
 - PrEP users are screened for bacterial STIs frequently due to follow-up requirements.
- On a population level, sexual risk compensation is a fallacy.





Sexual Risk Compensation



<u>iPrex</u>

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

Syphilis incidence also decreased in both study arms

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

PROUD

- Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection
 - UK randomized, open-label study
 - 275 MSM to start TDF/FTC immediately
 - 269 MSM to start TDF/FTC after 1 year
 - 86% HIV risk reduction
 - No difference between groups in STI incidence



Julia L. Marcus, David V. Glidden, Kenneth H. Mayer, Albert Y. Liu, Susan P. Buchbinder, K. Rivet Amico, Vanessa McMahan, Esper Georges Kallas, Orlando Montoya-Herrera, Jose Pilotto, Robert M. Grant. PLoS One. 2013 Dec

> McCormack S, et al. Lancet. 2016 Jan 2; 387(10013): 53–60. 18;8(12):e81997







As a society, we treat HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.





PrEP barriers - Providers

- Insufficient evidence of efficacy
- Inexperience with Truvada/lack of knowledge
- PrEP is cost-prohibitive
- PrEP is not a primary care activity ("not me")
- Unfamiliarity with PrEP candidates; inability to assess high HIV risk
- Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior)

- Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment)
- Patients perceived as nonadherent, and risk HIV resistance mutation development
- Personal ideology

Blumenthal J, et al. *AIDS Behav* 2015,19:802-810. Karris MY, et al. *Clin Infect Dis* 2014,58:704-712. Sharma M, et al. *PLoS One* 2014,9:e105283. Hakre S, et al. *Medicine (Baltimore)* 2016,95:e4511. Clement ME, et al. *AIDS Care* 2017:1-6. Martin J, et al. Abstract # 1447. IDWeek, San Diego, October 4-8, 2017. Imp B, et al. Abstract # 879, IDWeek, San Diego, October 4-8, 2017. Blackstock OJ, eta al. *J Gen Intern Med* 2017,32:62-70.





PrEP eligibility



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PrEP eligibility

Summary of Guidance for PrEP Use				
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users	
Detecting substantial risk of acquiring HIV infection:	 Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	 Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	 HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting) 	
Clinically eligible:	 Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 			
Prescription	Daily, continuing, oral doeses of TDF/FTC (Truvada), ≤90 day supply			
Other services:	 Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 			
	Do oral/rectal STD testing	 Assess pregnancy intent Pregnancy test every 3 months 	 Access to clean needles/ syringes and drug treatment services 	



https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility

	Men Who Have Se	x With Men	Heterosexual Women and Men	Injection Drug Users	
Detecting substantial risk	 Sexual p 	231	HIRI-MSM	Risk Index*	
High part High part High part Corr	Recent b High nur partners History c no cond	How old are you today (yrs)?	<18 years 18–28 years 29–40 years 41–48 years	score 0 score 8 score 5 score 2	
	Commer Doe	2	How many men have you had sex with in the last 6 months?	\geq 49 years >10 male partners 6–10 male partners 0–5 male partners	score 0 score 7 score 4 score 0
Clinically eligible:	- No - No - Do	3	In the last 6 months, how many times did you have receptive anal sex (you were	1 or more times 0 times	score 10 score 0
Prescription Other services:	 Foll HIV side 	4	the bottom) with a man? How many of your male sex partners were HIV positive?	>1 positive partner 1 positive partner <1 positive partner	score 8 score 4 score 0
	• At 3 • Eve • Do oral/re	5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times 0 times	score 6 score 0
ource: US Public Health Service. Preexposure proph		6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes No	score 5 score 0
		7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes No	score 3 score 0
				Add down entries in right column to calculate total score	Total score†

*To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: "In the past (time) have you had sex? (if yes), with men, women, or both?"

†If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.



https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility

	Men Who Hav	e Sex With Men	Heterosexu	ual Women and Men Injection Drug Users
Detecting substantial risk	 Sexual p 			HIRI-MSM Risk Index*
of acquiring HIV infection:	 Recent b 	1	How old ar	ure you <18 years score 0
	High nur		today	
	 Partners History d 			
	no cond			Medication Guide
	 Commer 			TRUVADA® (tru-VAH-dah)
		2	How ma	(emtricitabine and tenofovir disoproxil fumarate)
			you h	tablets
Clinically eligible:	• Do		in the	Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new
	 No 	3	In the las	information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.
	• Noi		how n	This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication
	• Do		did yc anal s	Guide section "What is TRUVADA?" for important information about how TRUVADA may be used):
Prescription			the bo	 to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and
Other services:	• Fol	4	How ma	 to reduce the risk of getting HIV-1 infection in adults who are HIV-negative HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
other services	• HIV		sex pa	What is the most important information I should know about TRUVADA?
	side		HIV F	If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you
	• At 3	5	In the las	stop taking TRUVADA.
	 Eve 		how n	 Do not stop taking TRUVADA without first talking to your healthcare provider. Do not run out of TRUVADA. Refill your prescription or talk to your healthcare provider before your TRUVADA is all
	 Do oral/re 		you h	 Do not full out of TROVADA. Renil your prescription of talk to your realiticare provider before your TROVADA is all gone.
			sex (y	 If your healthcare provider stops TRUVADA, your healthcare provider will need to watch you closely for several months to start your healthcare provider stops TRUVADA.
			with a HIV r	months to check your hepatitis B infection, or give you a medication to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking TRUVADA.
ource: US Public Health Service. P	reevposure proph	6	In the las	For more information about side effects, see the section "What are the possible side effects of TRUVADA?" in this
ource. US Public Health Service. Fi	reexposure propri	0	you u	Medication Guide.
			such a	Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection: Before taking TRUVADA to reduce your risk of getting HIV-1 infection:
		7	In the las	You must be HIV-negative to start TRUVADA. You must get tested to make sure that you do not already have
			have y	• Fourmust be HIV-negative to start TROVADA. Fourmust get tested to make sure that you do not already have HIV-1 infection.
			(amyl	Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.
				 Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like
				illness within the last month before starting TRUVADA or at any time while taking TRUVADA. Symptoms of new HIV-1
			10-00 August 10-0-07	infection include:
		that	*To identify r male patier	tiredness fever fever
			r male patier	 joint or muscle aches rash



https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility

	Sum	mary of Gu	idance fo	r PrEP Use				
	Men Who Hav	e Sex With Men	Heterosexu	al Women and Men	Injection Drug Users		1	
Detecting substantial risk	 Sexual p 	51 1.0		HIRI-MSN	I Risk Index*			
of acquiring HIV infection:	 Recent b High nur partners History o no cond 	1	How old a today	re you	<18 years Medication	score 0		
	• Commer	2	How ma you h		TRUVADA® (tru (emtricitabine and tenofovi tablet:	r disoproxil fumarate)		
Clinically eligible:	• Do • No • Noi • Do	3	in the In the lat how n did yc anal s	information. This informati your treatment. This Medication Guide pro Guide section "What is T	de before you start taking TRUVADA a ion does not take the place of talking t ovides information about two different RUVADA?" for important information nodeficiency Virus-1 (HIV-1) infection,	o your healthcare prov ways that TRUVADA n about how TRUVADA	ider about your medical condition o nay be used (see the Medication	Я
Prescription Other services:	Fol HIV side At 3 Eve	4	the bo How ma sex pa HIV p In the lat how p	HIV is the virus that cause What is the most import If you also have hepatitis stop taking TRUVADA	etting HIV-1 infection in adults who are as AIDS (Acquired Immune Deficiency ant information I should know abou s B virus (HBV) infection and take T A.	Syndrome). t TRUVADA? RUVADA, your hepat		-
ource: US Public Health Service. P	Do oral/re reexposure proph	6	you h sex (y with a HIV F In the la you u such a In the la	1. Men who hav Tell For A serodisc A recent se oth Bef	e sex with men, are sexually a ordant sex partner (i.e., a sex exually transmitted infection (S nt use of condoms during rece	partner living with GTI) with syphilis, g ptive or insertive a	HIV) gonorrhea, or chlamydia anal sex	
		mer	*To identify r male patier , women, o †If score is 1 vices; If score i	A serodisc A serodisc Inconsister drugs or bi A recent S A Persons who Share drug	women and men who are sex ordant sex partner (i.e., a sex nt use of condoms during sex isexual partner) TI with syphilis or gonorrhea inject drugs and have one of t g injection equipment of sexual acquisition of HIV (s	partner living with with a partner who he following chara	HIV) bse HIV status is unknown a	anacteristics. and who is at high risk (e.g., a person who in

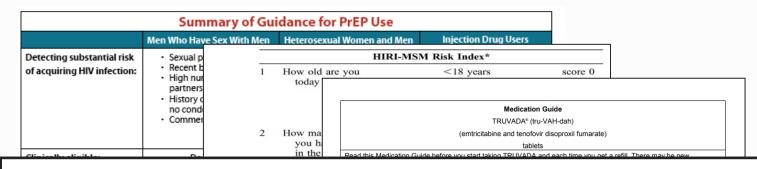
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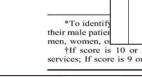




PrEP eligibility



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



· A recent STI with syphilis or gonorrhea

3. Persons who inject drugs and have one of the following characteristics:

- or 1 o Share drug injection equipment
 - Are at risk of sexual acquisition of HIV (see above)

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf





Recommendation comparisons

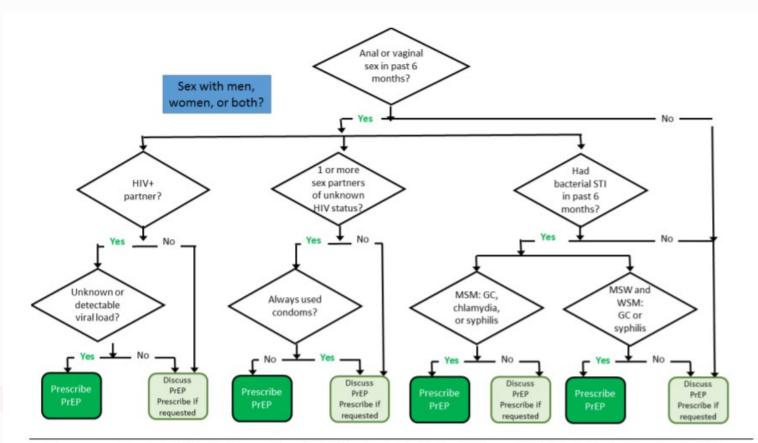
- 300 high risk young, black MSM (age 16-29) in Chicago
- 33 HIV acquisitions over 3 years
 - 52% met CDC eligibility for PrEP
 - 85% met HIRI-MSM eligibility for PrEP
 - 94% met drug company eligibility for PrEP
 - CDC guidelines: Low sensitivity, specificity (52%)
 - Drug company guidelines: High sensitivity, low specificity (15%)

Lancki N et al. AIDS, 2018



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Discuss with everyone!



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2021 Update Clinical Practice Guideline



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

41



What about U=U?







U=U

- Those who have an undetectable viral load have effectively no risk of transmitting the virus.
- This is a consensus of HIV experts worldwide, CDC, NIH, IDSA/HIVMA, common knowledge in the medical community.
- Combined data from 4 studies (HPTN 052, OPPOSITES ATTRACT, PARTNER and PARTNER2)
 - Among sero-discordant couples where the partner living with HIV had a durably undetectable viral load:
 - zero transmission among over a hundred thousand condomless sex acts
 - Results similar in both male-female and male-male partnerships





U=U

Is PrEP necessary in this situation?

- Consider *durable* viral suppression
 - Contributing factors include adherence, history of virologic failure, follow-up interval of the HIV-positive person
- Consider non-monogamous sex
 - In U=U studies, HIV transmissions DID occur, but were linked to sex between HIV-negative participant and HIV-positive individual not involved in the study
- <u>Always</u> weigh risks and benefits





Special considerations (TDF/FTC and TAF/FTC)

- Pregnant or breastfeeding women
 - Pregnancy Category B (No known risk)
 - Minimally secreted in breastmilk, not contraindicated in breastfeeding

Chronic HBV

- TDF/TAF and FTC are active against HBV
- Abrupt withdrawal could cause HBV flare
- Stopping requires careful monitoring and observation
- Chronic Renal Failure (CrCl <60mL/min)</p>
 - Don't use TDF/FTC; safety has not been adequately determined
 - Can use TAF/FTC for CrCl >30mL/min





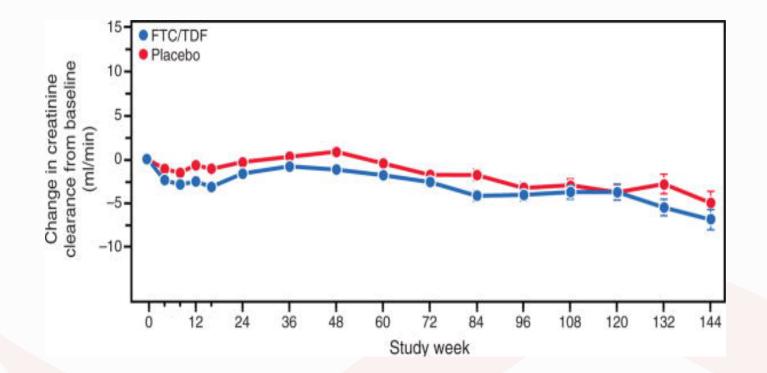
PrEP medication counseling



PrEP Medication Counseling

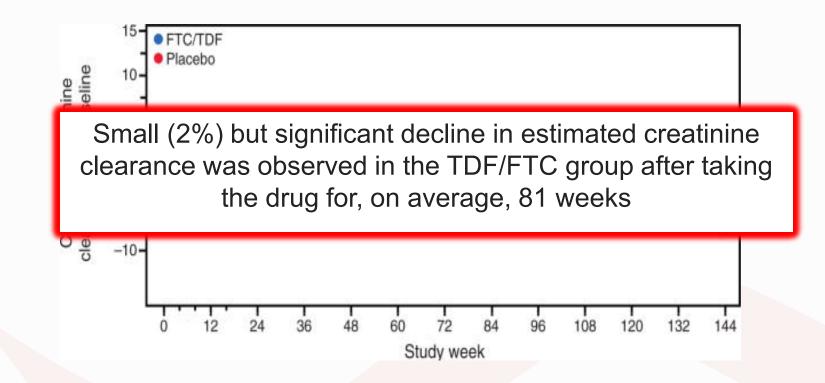
- Dosing
 - One tab daily, with or without food
- Adherence, and its relationship to efficacy
- Time to effectiveness
 - 7-10 days for men, 21 days for women
 - Barrier protection especially needed during that time
- Adverse effects
 - Nausea, vomiting, diarrhea, loss of appetite, weight loss
 - Fatigue,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







iPrEX, 2013





iPrEX, 2013

Assessment		Forearm			Hip		Li	umbar Spine	
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			< 0.001			< 0.001
Enrollment	-0.75	-0.58		0.44	0.53		-0.72	-0.59	
6 mo	-0.77	-0.50		0.33	0.57		-0.84	-0.45	
12 mo	-0.79	-0.48		0.33	0.54		-0.77	-0.56	
18 mo	-0.93	-0.27		0.17	0.77		-0.92	-0.43	
24 mo	-0.92	-0.13		0.21	0.74		-1.11	-0.37	
z Score			0.004			< 0.001			<0.001
Enrollment	-0.70	-0.54		0.45	0.54		-0.67	-0.54	
6 mo	-0.73	-0.45		0.35	0.58		-0.80	-0.41	
12 mo	-0.72	-0.42		0.34	0.55		-0.74	-0.53	
18 mo	-0.88	-0.21		0.18	0.78		-0.88	-0.41	
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.



Assessment		Forearm			Hip		Li	umbar Spine	
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
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Enrollment	-0.75	-0.58		0.44	0.53		-0.72	-0.59	
6 mo	-0.77	-0.50		0.33	0.57		-0.84	-0.45	

Significant decline in T scores and z scores for BMD at the forearm, hip, and lumbar spine in participants who received TDF/FTC, as compared with those who received placebo

6 mo	-0.73	-0.45	0.35	0.58	-0.80 -0.41
12 mo	-0.72	-0.42	0.34	0.55	-0.74 -0.53
18 mo	-0.88	-0.21	0.18	0.78	-0.88 -0.41
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.



Table 3. Bone Mi	neral Density Sco	res.*							
Assessment		Forearm			Hip		Lu	umbar Spine	
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001

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.





PrEP laboratory monitoring





HIV screening

- At baseline, 4th generation HIV Ag/Ab combination assay
- During PrEP maintenance, HIV Ag/Ab AND HIV RNA PCR are now recommended
 - Incident HIV infections during PrEP use may exhibit lower viral replication and longer time to antibody production (seroconversion)
- Routine HIV RNA PCR may not be readily available or affordable
 - Providers should use tests that are available to them to continue PrEP provision

Donnell D, et al. The effect of oral preexposure prophylaxis on the progression of HIV-1 seroconversion. AIDS. 2017;31(14):2007. 78.

Marzinke MA, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. Infect Ds. 2021;





A year of oral PrEP

Encounter	To do
Month 0	 Screen for HIV Confirm HBV and HCV status Check serum creatinine Screen for STIs Counseling Prescribe
Month 3	Screen for HIVCounselingPrescribe
Month 6	 Screen for HIV Screen for STIs Counseling Prescribe
Month 9	Screen for HIVCounselingPrescribe
Month 12	 Screen for HIV Screen for STIs Check serum creatinine Counseling Prescribe

Labs*:

- HIV screen: 5
- Serum creatinine: 2**
- STI screen: 3

*Lipids Q12 months if taking TAF/FTC **Serum creatinine should be done Q6 months if age ≥50 years or who have an CrCl <90 mL/min at initiation

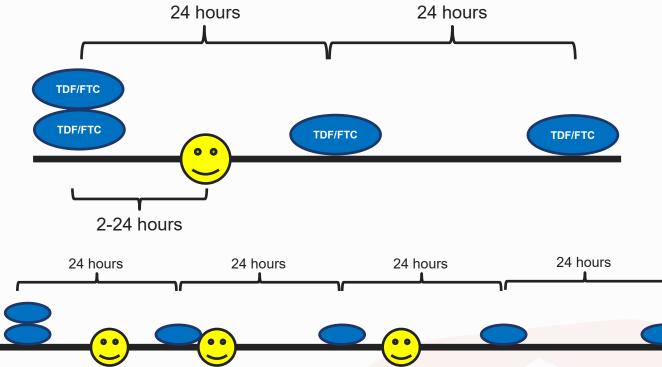
Prescriptions/Refill authorizations: 5

Discussions: 5+

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf



Event-Driven (2-1-1) Dosing – TDF/FTC ONLY!



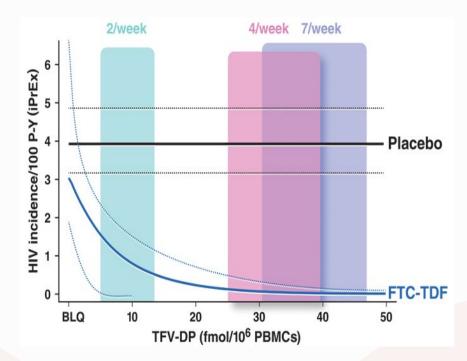
- Off-label dosing to consider
- Continue 1 pill/day until 48 hours from event
- If <7 days between last pill and new event, resume one pill/24 hours (no need to double-dose)

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf





Dosing matters



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





Financial aspects of PrEP





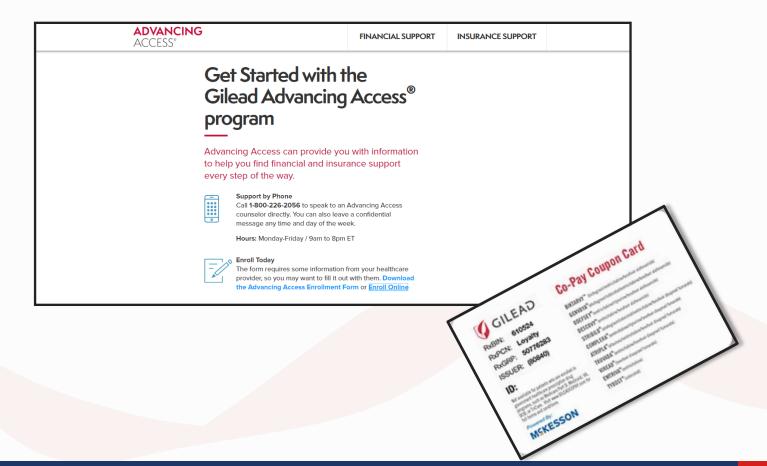
PrEP coverage

- Most insurance plans cover TDF/FTC, most cover TAF/FTC (though fewer cover brand medication)
 - Variable copays
- Medicare/Medicaid cover PrEP
- Gilead Advancing Access Program Copay Assistance
 - \$7,200/calendar year of copay assistance
 - No income limitation, federal beneficiaries excluded
- Gilead Advancing Access Program Medication Access
 - Full drug coverage if income <500% federal poverty level</p>
 - Primary option for uninsured patients





Copay Assistance





Medication Assistance Program

ADVANCING ACCESS®							MENT F0		PAGE 1 OF :
1. REQUESTED PATIENT SUPPORT (REC	UIRED)						CHECK A	LL BOXES TH	HAT APPLY
Benefits Investigation		Prior Au	uthorizatio	an an	d Appeals Information		Co-pay Coupon P	Yogram Enro	lment
Patient Assistance Program (PAI	9) or Medicatio	on Assistance Pro	ogram (Mi	AP) E	ligibility Screening				
2. GILEAD MEDICATION PRESCRIBED (I	REQUIRED)								
Product Name:				m	ç.				
If requesting TRUVADA', please indicat	e for:	Treatment	Pr	EP/P	revention				
3. PATIENT INFORMATION (REQUIRED)									
First Name:	L	ist Name:			ML	Pr	eferred Language	6	
Address:		Apt/Unit a			City:	_			
State:		Zip Code:			Phone #:		SSN# (Last	4 digits):	
Email:					DOB:				
Alternate Contact Name:					Phone #:		Relationshi	ip:	
CONTACT AUTHORIZATION									
I authorize Advancing Access to leave	a detailed me	issage, including	the name	ntos	ty prescription, if I am u	navailabl	e when they call.	Yes	No
4. INSURANCE INFORMATION (REQUIR	ED)			PLEA	SE INCLUDE A COPY O	F THE FF	RONT AND BACK	OF INSURA	CE CARD(S)
Patient is insured (Please fill out all below. Attach copy-front and back	of the applical	ole insurance inform d.)			Patient is uninsured SEE OPTIONAL "PATI	le, no heal	th insurance through	any public or pr	type peyerl
Primary Insurance:				Is	this a Medicare Part D	plan?	Yes	No	
Plan name:				In	surance Phone Number	6			
Subscriber Name:		Policy Holder Name:				Policy	Holder Inship to Patient:		
Policy #:	Group #:			R	x Bin #:		Rx PCN #:		
Check box if patient has second	ary insurance	coverage and fa	x a copy	of ins	urance cards. If availabl	e.	_		
		-		_					
5. PRESCRIBER INFORMATION (REQUI Prescriber Name:	RED)								
Address					acility Name:				
Address:	Zip Code:			-	ty: ffice Contact:				
Phone #	ap coor.			-	ande Contact.		NPLE		
Tay ID #					ate License #:		in the		
			_	1		_			
6. DIAGNOSIS/MEDICAL INFORMATION					M	JST BE C	OMPLETED BY H	EALTHCARE	PROVIDER
Diagnosis (Please include ICD code);									
7. PRESCRIBER CERTIFICATION AND ST	ATEMENT OF	MEDICAL NECE	ESSITY						
By signing this form, I certify that I am presc patient and that it will be used as directed. I. of my knowledge. I agree that I shall not see Program ("PAP:MAP") from any government	ibing Gilead m certify that I wil k reimburseme program or thin	dication for the pai be supervising the nt for any Glead m d-party insurer.	tient identif a patient's tr adication d	led in reatm ispen	Section 3.1 certify that this ents and verify that the info sed to the patient through !	prescript rmation p the Patient	ion medication is me rovided is complete t Assistance Program	dically necess and accurate t /Medication A	ary for the to the best salatance
If prescribing TRUVADA for PHEP", I certify the applicant's care plan. As part of my applicant I certify that I have received the appropriate of	witten authoriza	tion from the nation	at in accord	lenne :	with the Health Insurance P	netability a	ent de countability de	1 of 1996, anni	reble state
health information privacy law(s), and any oth the purposes of: 1) verifying the patient's insu- support, and refermal support as needed; 4) is patient's prescription medication or to evalua									
PRESCRIBER SIGNATURE (REQUIRED							DATE		
© 2017 Glead Sciences, Inc. All rights reserved	ADMC0300 1	5/17							

PATENT NAME: DATE OF BRITH B NTENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH NPORMATION (REQUIRED) Lunderstand that I must complete this enrollment form before I can receive assistance through Gilead Sciences. Inc.'s

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

I understand that it must complete this enrollment form before I can receive assistance through Gilead Solences, Inc. S Advancing Access (Program") and the Patient Assistance Program/Medication Assistance Program/(PaP/NAP). As part of this process, Gilead and its agents and contractors (collectively, Gilead") will need to obtain, review, use and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP/NAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization.

PAGE 2 OF 3

Information to Be Disclosed: Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV-related status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form.

<u>PersonsAuthorized to Disclose My Information</u>: My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization.

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

Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made to Gliead so that Gliead may use and disclose the PHI for purposes of: 1) completing the enrollment process and verifying my enrollment form; 2) establishing my eligibility for benefits from my health plan or other programs; 3) providing linancial assistance, support, and referral support, and communicating with my health plan or other programs; 3) providing linancial assistance, support, and referral prescription medication to me; 4) contracting me to evaluate the effectivenes of the Program and/or the PAPMAR; 5) for Gliead's internal business purposes, including quality control and support enhancing surveys; and 6) to send me marketing information, offers, and educational materials related to my treatment and/or my prescription medication, including the customer relationship marketing program (this use of my personal information is optional and by checking the box under the signatures below, Imavy oth in.).

Lunderstand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure. Lunderstand that there that I may relues to sign this authorization and that if I relues, may feliphtilly for health plan benefits or ability to obtain treatment from my healthcare provides will not change, but I will not have access to the support offered by Program and/or the PAP/IMAP. I also understand that I may cancel this authorization at any time by notifying Gilead in writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If Lancel, Gilead will stop using this authorization to obtain, use or disclose my PHI after the cancellation date, but the cancellation will not affect uses or disclosures of any PHI that have already been made pursuant to this authorization before the cancellation will not affect uses or disclosures of any pHI that have already been made pursuant to this authorization before the cancellation at a not method to accey of this signed authorization, which expires the earlier of two (2) years from the date it is signed by me or other time period required under the laws of the state in which I reside.

atient Representative's Relationship to Patient:	
atient Representative's Name (if signing for the patient):	
IGNATURE OF PATIENT'S REPRESENTATIVE (REQUIRED):	DATE:

By checking this box, I agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my

ATIENT NAME:					DATE OF BIRTH:
B. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPL	LYING FO	R THE	PATI	ENT AS	SISTANCE PROGRAM/MEDICATION ASSISTANCE PROGRAM (PAP/M
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, to If there is no household income, indicate how the patient/household is i	being supp	W2, ins contect	t 2 pe	y stubs,	etc.
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:
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Ready, Set, PrEP

US Dept. of Health and Human Services Program

- No-cost PrEP provider if the patient:
 - Tests negative for HIV;
 - Has a valid prescription
 - Does not have health insurance coverage for outpatient prescription drugs
- Does not cover costs of visits or labs
- Easy to apply:
 - Online: GetYourPrEP.com
 - By phone: 855.447.8410







STOP PrEP

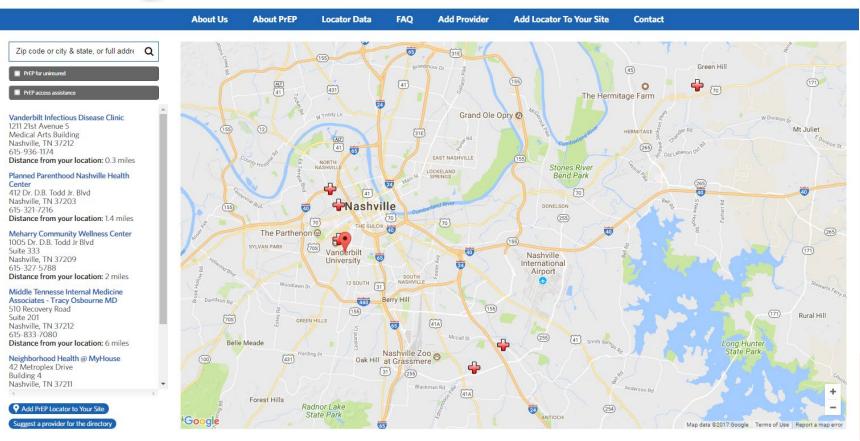
- The patient doesn't want it
- Behavior or life situations have changed that lower risk for HIV infection
- Intolerable adverse events/toxicities
- HIV-infection





PrEP Locator

PrEP Locator **Q** Find Your Provider

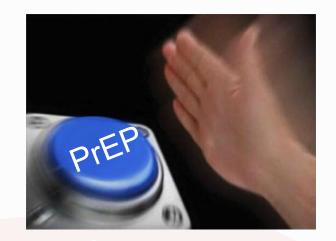


https://preplocator.org



Conclusion

- PrEP is a component of primary care
- PrEP is an extremely effective preventive strategy for both HIV and STIs
- Understand PrEP prescribing guidelines
- There are some adverse effects, but PrEP is generally very well-tolerated
- PrEP requires an ongoing patientdoctor relationship
- Ask for help! <u>sean.g.kelly@vumc.org</u>







Questions?

