





# PrEP and Insurance Coverage



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# Disclosures and Objectives

No disclosures

- Objectives
  - 1. PrEP 101
  - 2. Accessing care for persons with insurance
  - 3. Accessing care for persons without insurance
  - 4. Cases



PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

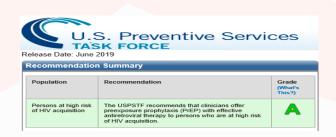
A CLINICAL PRACTICE GUIDELINE

# HIV PrEP Option #1

- Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg has been shown to be safe and effective in reducing the risk of HIV acquisition in at risk adults(AI)<sup>1</sup>
  - Truvada® (FDA approved) pts with eCrCl of ≥60 ml/min
  - FDA approved for adolescents over 35 kgs(2018)









### PrEP: Does it Work?

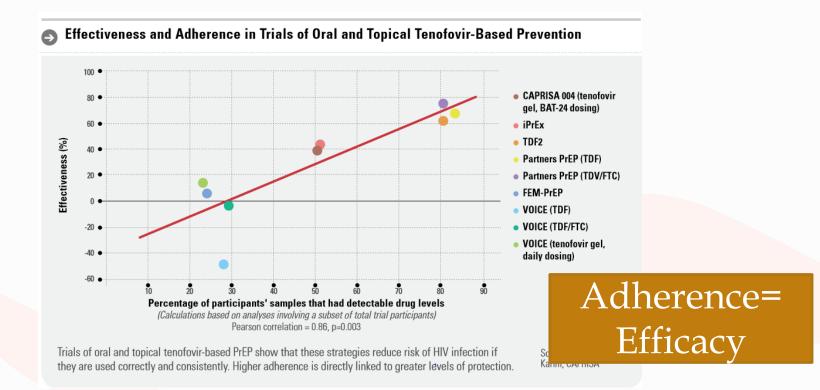
PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES

	A CLINICAL PRACTICE GUIDEI				
Trial	Where	Who	What	Efficacy	
1. iPrEx n=2499	SA, US, South Africa, Thailand	MSM high risk	TDF-FTC or placebo	44% TDF-FTC	
2. Partners PrEP n=4747	Kenya, Uganda	Discordant hetero couples	TDF, TDF-FTC or placebo	67 -75% (TDF, TDF/FTC) •Men 84%;Women 66%	
3. US MSM safety Trial, n=400	US	MSM	TDF or placebo Early vs delay	Not reported ; 0 infections on TDF	
4. TDF2 n=1219	Botswana	Hetero men or women	TDF-FTC or placebo	62.2% all •80% men •49% women (NS)	
5. FEM-PrEP n=2120	Kenya, South Africa, Tanzania	Women	TDF-FTC or placebo	Stopped early due to lack of efficacy	
6. VOICE n=5021	Uganda, South Africa, Zimbabwe	Heterosexual women	TDF gel, placebo gel, TDF, TDF-FTC, placebo pill	TDF gel/pill stopped, lack of efficacy	
7. West African Trial n=859	West Africa	Hetero women	TDF vs placebo	65% ( NS, stopped early)	
8. Bangkok TDF n=2413	Thailand	IVDU	TDF or placebo	49% TDF	



# PrEP: Efficacy and Adherence

- If drug detected in blood, effectiveness of PrEP = <u>90-92%</u>
  - 92-100% if levels equivalent to daily use<sup>2</sup> (Post Hoc iPrEx)
  - 0 conversions if at least 4 doses taken<sup>3</sup>





### PrEP: The Reality

Open Label Studies with good outcomes

			Efficacy by blood
Recent Trials	Participants (n)	Efficacy Estimates %	detection of drug
PROUD (UK)	MSM (500)	86 (90% CI=64-96)	-
IPERGAY (France)	MSM(400)	86 (95% CI=40-99)	-
KAISER(US)	99% MSM(657)	100 (5104 py of f/up)	-
SF STRUT (Nurse led-US)	99% MEN (1252)	100	-
Demo (3 centers, US)	MSM (430) MtF (5)	HIV incidence 0.43 per 100 py	2 seroconverters- levels equivalent to <2 doses/wk
iPrEx OLE	MSM	49 (95% CI: 0.26-1.01)	If 4-7 doses/wk, efficacy =100%



PROUD: McCormack S, et al. Lancet 2015 STRUT Gibson, S. et al. AIDS 2016 Kaiser: Volk, J et al. CID 2015, Marcus CID 2017. IPERGAY: Molina, J. et al. NEJM 2015;373:2237-46 Demo - Molina Lancet HIV. 2017

### PrEP: Who Needs It?

### **MSM** Commercial sex workers HIV+ partner Recent STI Multiple partners Inconsistent/No condoms

# Heterosexual Men and Women

- Commercial sex workers
- HIV+ partner
- Recent STI
- Multiple partners
- Inconsistent/No condom use
- High prevalence area

## Injection Drug Users

- HIV positive injecting partner
- Sharing needles/inject ion equipment

# Transgender People

Trans women of color<sup>2</sup> (National HIV/AIDS Strategy 2010, 2015)

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE

FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV: Recommendations for use in the context of demonstration projects

July 20







1. https://www.cdc.gov/hiv/risk/prep/index.html (2017 guidelines)

2. Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in US . AIDS Behav 2008

3. https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s cid=mm6827a1

#### https://www.cdc.gov/hiv/p Work Flow df/library/factsheets/prep 101-consumer-info.pdf

(Page 1 is in English, Page 2 is in Spanish)

July 2019

#### **PrEP 101**

Are you HIV-negative but at very high risk for HIV? Taken every day, PrEP can help keep you free from HIV.

#### What Is PrEP?

- · PrEP, or pre-exposure prophylaxis, is daily medicine that can reduce your chance of getting HIV.
- PrEP can stop HIV from taking hold and spreading throughout your body.
- · PrEP is highly effective when taken daily as prescribed. PrEP is much less effective if not taken consistently.
- · Only condoms protect against other STDs like syphilis and gonorrhea.



#### Is PrEP Right For You?

PrEP may benefit you if you are HIV-negative and ANY of the following apply to you.

#### You are a gay/bisexual man and You are a heterosexual and

- · have an HIV-positive partner.
- have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown-and
- have anal sex without a condom, or
- o recently had a sexually transmitted disease (STD)

- have an HIV-positive partner.
- · have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown-and
  - o don't always use a condom for sex with people who inject drugs, or
  - o don't always use a condom for sex with bisexual men.

#### You inject drugs and

- · share needles, syringes, or other equipment to inject drugs.
- · are at risk for aettina HIV from sex.

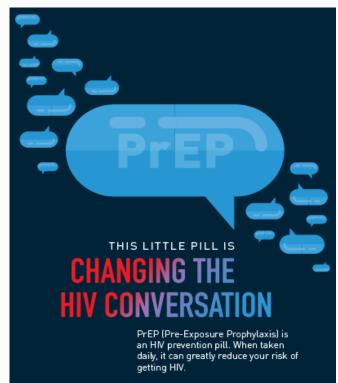


#### -Visit Your Healthcare Provider

- . To find out if PrEP is right for you.
- If you have any symptoms while taking PrEP



Find your **PrEP** Champion



There are more HIV prevention options than ever before. Talk to your doctor about which options are right for you.









SURE

Start '

Stop

DAILY Prep + CONDOMS







### PrEP Workflow







### **HIV PrEP Implementation Toolkit**

1 vs 2 visits

# Bolded items mandatory

#### **PrEP Orientation Visit:**

- Discuss PrEP use
- Review insurance coverage/med. assistance
- Perform baseline laboratory tests:
  - HIV Ab/Ag screen^ (4<sup>th</sup> generation)
  - o Cr
  - Hepatitis Bs Ag/Ab and cAb
  - Hepatitis C Antibody
  - RPR/Trep Ab
  - Triple site GC/CH testing- Urine,
     Rectal, Oral (based on exposure)
  - Pregnancy test (if female)

#### **Initial Provider Visit:**

- Discuss PrEP use (7 day interval before adequate levels in rectal tissue and 20 days for vaginal tissue/blood; compliance; SE)
- Risk reduction counselling, condoms
- PrEP Clinic Questionnaire(initial)
- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (start within 7 days of HIV screen)



# PrEP Workflow

### **Every visit(Q 3mths)**

- Provide condoms
- HIV Ag/Ab → refills
- Assess adherence
- Risk reduction counseling

Decide who sees the person





#### **HIV PrEP Implementation Toolkit**

Bolded items mandatory

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- 30-day supply of PrEP (start within 7 days of HIV screen)

#### 30-day visit:

- Adherence review with nurse/ PharmD, risk reduction counselling, assess side effects
- Cr

60-day supply of PrEP

Optional UA

#### 3-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit, risk reduction counselling, condoms
- HIV Ab/Ag Test, Pregnancy test, STI screen in MSM^(RPR/Trep Ab, GC/CH(triple site))

90-day supply of PrEP

#### 6-month visit/ 12 month visit:

- PrEP Clinic Questionnaire (long)
  - Provider visit, risk reduction counselling, condoms
- HIV Ab/Ag , Pregnancy test, Cr, RPR/Trep Ab, GC/CH( triple site), Hep C ab annually

90-day supply of PrEP

#### 9-month visit:

- PrEP Clinic Questionnaire (short)
- · Provider visit, risk reduction counselling, condoms
- HIV Ab/Ag, STI screen in MSM(RPR/Trep Ab, GC/CH(triple site))

90-day supply of PrEP

#### After the 12 month visit: (Re-evaluation of need for continuing PrEP)

Q 3 monthly visit with Adherence nurse/ Pharm D, risk reduction counselling, , condoms.

- PrEP Clinic Questionnaire (short)
- HIV ab/ab q 3 monthly and STI screen q 3 monthly in MSM
- 90 day supply of PrEP

Q 6 monthly visit with Provider

- · Pregnancy test, Cr, RPR/Trep Ab, GC/CH( triple site) ,Hep C
- 90-day supply of PrEP, condoms





### PrEP Workflow: Adherence



Efficacy



https://www.caringvillage.com/2018/02/09/the-top-five-medication-management-apps/https://www.ripplephx.org/?p=5234















# Adherence Counselling What to expect

- Symptoms
  - Flatulence, nausea / GI upset
  - Headache and rash
  - Arthralgia
- Start up syndrome resolves within 4-6 wks
  - Use OTC medications
- Uncommon
  - Drop in bone density(TDF)
  - Renal dysfunction (subclinical), rare
     Fanconi syndrome
  - Lactic acidosis
  - Transaminitis



https://www.cdc.gov/hiv/pdf/Pr EP\_GL\_Patient\_Factsheet\_Tr uvada\_English.pdf



#### What special dietary instructions should I follow?

Continue your normal diet unless your doctor tells you otherwise.

#### What should I do if I forget a dose?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

#### What side effects can this medication cause?

You may experience the following side effects while taking Truvada:

- upset stomach
- headache
- vomiting
- . loss of annotite

These side effects usually fade during the first month of taking Truvada for PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

Truvada may cause other side effects. Some side effects can be serious. Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- · fever or chills especially with
- · sore throat, cough, rash or other signs of infection



3 Solomon et al. Changes in renal function ....PrEP. AIDS. 2017

4 Liu et al. Bone mineral density in .. PrEP ... in San Francisco. PLoS One. 2011 5 PROUD: McCormack S, et al. Lancet 2015

## Bone Health (TDF)



- Small (~1%) decline in BMD occurred in first few months → either stabilized or returned to normal <sup>1,2</sup>
  - iPrEx trial (TDF/FTC) & CDC PrEP safety trial in MSM
  - No increase in fragility (atraumatic) fractures over the 1-2 years
- DEXA scans or other assessments are NOT recommended



### PrEP: Option #2

- TAF/FTC –FDA approved for at-risk adults and adolescents (≥35 kg), excluding individuals at risk from receptive vaginal sex. (October 2019)
  - Not yet incorporated into guidelines

eCrCl > 30 mL/min



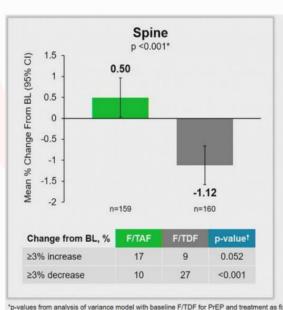
Not an option for Cis Women Trans men(yaginal sex)

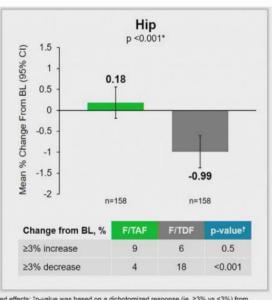


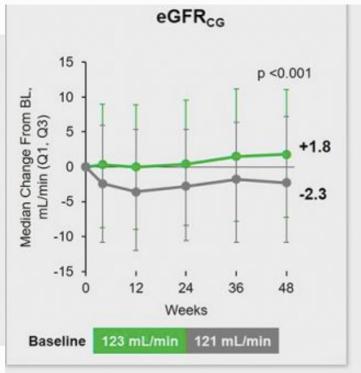
### TAF vs TDF

### Bone/Kidney Health

- RCT of Truvada<sup>®</sup> versus Descovy <sup>®</sup> for PrEP
  - MSM and TGW (Enrolled ~6000: 74 TGW); followed 96 wks
  - 22 HIV transmission (7 TAF and 15 TDF)







'p-values from analysis of variance model with baseline F/TDF for PrEP and treatment as fixed effects; \*p-value was based on a dichotomized response (ie, ≥3% vs <3%) from Cochran-Mantel-Haenszel test for nominal data (general association statistic) adjusting for baseline F/TDF for PrEP, BL, baseline.

### Case 1

- 29 y/o cis-male, MSM come to office
  - Presented there with 'drips'
  - Got treated with ceftriaxone IM and azithro
  - Urine GC was sent
  - HIV test negative, CrCL >60

- Should PrEP be discussed
  - 1. Yes
  - 2. No



## Case 1: PrEP options for him?

- Daily TDF/FTC (Truvada®)
- 2. Daily TAF/FTC (Descovy ®)
- 3. Defer PrEP, no time



### Case 1 Workflow

- Get labs
- Review insurance coverage
  - Has insurance
  - ? Pay for labs
  - ? Pay for Visit
  - Can patient afford visits

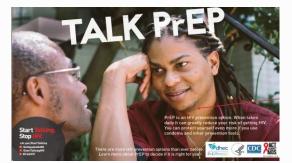


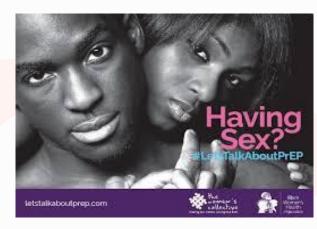














### Insurance

- Group Insurance Plans
  - Company
  - Organization
- Marketplace Insurance Plans
  - Individual
  - Family
  - Small Business



### **Covered Services?**

- Preventative Care Benefits
  - Screening\*:
    - Chlamydia, Gonorrhea, HepB, HepC, HIV, Syphilis
  - Sexually Transmitted Infection (STI) Counseling
  - Immunization Vaccines



# Acceptable Billing Codes



Palmetto Health USC

#### **Prep Implementation Toolkit**

#### Billing Code Guide:

Type of visit	Code descriptor				
STI Prevention	Contact with and suspected exposure to HIV				
	Contact with and suspected exposure to infections				
	with predominantly sexual mode of transmission				
	Contact with and suspected exposure to viral				
	hepatitis				
	High risk Heterosexual Behavior				
	High risk Homosexual Behavior				
	High risk Homosexual Behavior				
STI Counselling	Counselling Counselling related to patients				
	and orientation				
	Counselling related to combined concerns regarding sexual attitude, behavior and				
	orientation				
	Other sex counselling	CPT codes for Service			
	Sex counselling, unspecified				
	HIV counselling	Type of service			
		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
STI Screening Test	Encounter for pre-procedu				
	Encounter for screening for	Evaluation and Mana			
	predominantly sexual mod				
	Encounter for HIV screen				
	Encounter for screening for				
	parasitic diseases				
	Encounter for screening for				

#### CPT codes for Services

ICD -10

Z20.6

Z20.2

Z20.5

Z72.51

Z72.52

Z72.53

Z70.1

Z70.3

Type of service	Description (document /bill based on time and	CPT code
	complexity )	
Evaluation and Management	Initial visit and assessment	99201-99205
	Prescription visit	99211-99215
	Quarterly follow-up visit	99211-99215
	Annual follow visit	99211-99215
Preventative Medicine and Risk	Initial comprehensive preventative medicine	99384-99387
Factor Reduction Visits	services	
	Comprehensive preventative medicine services	99394-99397
	for established patients	
	Preventative medicine counselling and/or risk	99401-99404
	factor reduction interventions	



### Medication Assistance

- Insured (Rx coverage)
  - Commercial/Private
    - Gilead Co-pay Coupon Program
    - Patient Advocate Foundation
      - 400% FPL
  - Government/Public
    - Good Days
      - Medicare Part D or Military
        - 500% FPL
    - Patient Advocate Foundation
      - 400% FPL



### Case 2

- 25 y/o Trans-woman visits your office with rash
- 1 male partner, condomless sex
- No new lotions or soaps, No meds
- WBC normal
- PHx
  - GC positive in 2018, Chla 2019,



# Case 2- PrEP options for her?

- Daily TDF/FTC (Truvada®)
- 2. Daily TAF/FTC (Descovy ®)
- 3. Defer PrEP since not cis-gender



# PrEP: Transgender

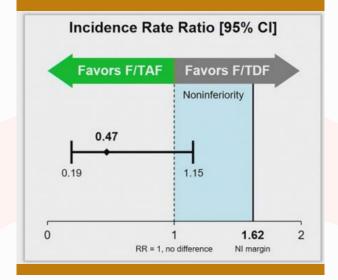
iPrEx Trial (TDF/FTC) had 339 Transwomen (MtF) only

- MtF more frequently reported transactional sex, receptive anal intercourse without condom, >5 partners in the past 3 months
- Overall adherence, less for MtF
- if > 4 tablets/week, rate of infection per 100,000 pt/yr = 0

# PrEP: Transgender Discover Trial and Patient Population

- RCT of Truvada® versus Descovy® for PrEP
  - MSM and TGW
  - Enrolled ~6000
    - 74 TGW
  - Followed- 96 wks
  - 9% black
  - High rates STI and chemsex

- 22 HIV transmission
- 7 TAF and 15 TDF



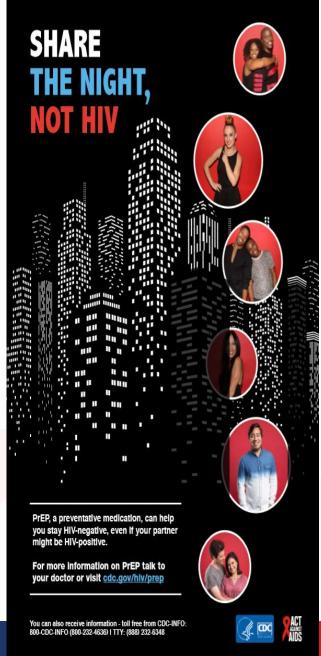
CROI 2019-Discover: Phase III RCT of F-TAF vs. F-TDF for PrEP



### Case 2 Workflow

- Get labs
- Review insurance coverage
  - Does not have insurance
  - ? Pay for labs
  - ?Pay for meds
  - Can patient afford visits

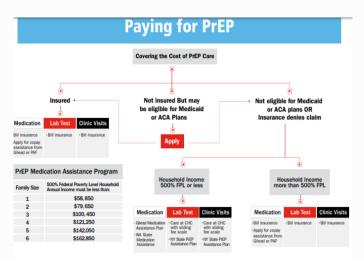






### Medication Assistance

- Un-insured (Rx coverage)
  - Gilead Patient Support Program
    - 500% FPL
  - Ready, Set, PrEP
    - Not income based
    - Designated Pharmacy



#### ABBREVIATIONS

ACA - Affordable Care Act

FPL - Federal Poverty Level

CHC - Community Health Center PAF - Patient Advocate Foundation

#### DEFINITIONS

PrEP: Daily pill to prevent HIV infection (pre-exposure prophylaxis)

Co-pay: Fixed amount to be paid by insured person per prescription

Co-insurance: Fixed percentage of prescription cost to be paid by insured person

Deductible: Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

#### Prep Medication assistance program:

#### (Gilead Sciences)

People eligible for this program must

- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier.
- · Be resident in the US (social security number not required)
- Have family income ≤ 500% of the federal poverty level

#### Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient's home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- · Eligibility must be confirmed every 6 months by the provider

To apply for health insurance on the federal exchange: www.healthcare.gov
Community Health Center Locator: findshealthcenter.hrsa.gov
NASTAD on-line tool to assist with paying for PrEP at PrEPcost.org

Gilead Sciences: Medication Assistance Program and Co-Pay Assistance - www.truvada.com/how-to-get-truvada-for-prep/truvada-cost Patient Advocate (PAF) Foundation: Co-Pay Relief Program - www.copays.org/diseases/hiv-aids-and-prevention







 https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-PayingforPrEP-flyer.pdf



### Case 3

- MSM on truvada for PrEP
- Monogamous serodiscordant relationship.
  - Partner is undetectable
- After discussing U=U, patient prefers to stay on PrEP

### What do you recommend for PrEP

- 1) Staying on Truvada®
- 2) Switching to Descovy ®
- 3) No PrEP since U=U



# Work flow of switching

#### Insured

- Check coverage, prior authorization
  - Clinic staff- COMVERMYMED
  - Specialty pharmacy partner
- Copay cards available
  - https://www.gileadadvancingaccess.com/copay-coupon-card
  - Covers up to \$7,200
  - Not eligible government healthcare programs (Medicare Part D, Medicaid, TRICARE, or VA)
    - SC Medicaid covers TAF/FTC and TDF/FTC

Copay Cards transfer from TDF--> TAF

For switch
TDF→TAF
PA needed
- United HC; cig;
Anthen



Some info complements of Michael DeMarco Gilead Sciences, Inc.





# **Submitted Cases**

### **Submitted Case-1**

Age: <u>29</u> F	Race: <u>AA</u> Gende	r:_ <mark>Male</mark> Femal	e Tra	ns-female Trans-n	nale		
Concomitant Medi	Concomitant Medical Diagnosis Current Medications						
Genital Herpes (rect	al)		Emtri	Emtricitabine/Tenofovir alafenamide			
Hemorrhoids							
Self-reports sexual a	addiction						
Hx of childhood mol	estation						
Insurance:   Yes	□ No						
Copay assistance n	eeded 🗆 Yes 🗆 🗈	No					
Drug assistance needed ☐ Yes ☐ No							
Risk factors: (Check all that apply)							
MSM □bisexual	Recent STI	Multiple sex		HIV positive □	IVDU/Sharing□		
		partners		partner	needles		
Inconsistent  condom use	Commercial sex ☐ work						



### Submitted Case-1 continued

Health Maintenance		Description		Risk Reduction Counselling/Intervention					
1. Smoking					☐ Yes ☐ No				
Use of Alcol	hol/Amount		social		_	□ Yes □ No			
<ol><li>Substance l</li></ol>	Jse		marijuana		☐ Yes ☐ No				
4. Mental Heal	th Assessment		,	☐ Yes ☐ No					
	Contraception				☐ Yes ☐ No				
<ol><li>Condoms us</li></ol>	se					] Yes □ No			
Laboratory Test res									
HIVAg/Ab screen	negative	Cr 0.93			$\perp$	CrCl	130		
Hepatitis Bs Ag	negative	Hepati	itis Bs Ab	positive		Pregnancy test			
HCV ab with reflex	negative								
STI screen Date /		Date /	/Result						
Urine GC/CHL 1/16/2		2020 negative							
Throat GC/CHL 1/16/20			2020 negative		ヿ				
		2019 positive		$\neg$	1/16/2020 negative				
RPR 1/16/2		2020 1:32							
Medication SE (If already on tenofovir/emtricitabine)									
Headache □ Yes □ No Arthral			ılgia □ Yes □ No		Т	<u> </u>			
Nausea/vomiting ☐ Yes ☐ No Crinc			rease 🗆 `	Yes □ No	╛				

Other Questions \_\_This patient has insurance, but the insurance will not cover PrEP. Gilead was able to offer this patient drug assistance for Descovy. Patient refuses to take Truvada again because he reports large painful bowel movements. Patient refused to believe he had rectal HSV that was causing the pain.



### Additional Resources

- http://schivtc.med.sc.edu/ prep/index.asp
  - Telehealth- 2<sup>nd</sup> Wednesday
- https://www.cdc.gov/hiv/risk/prep/index.html
- DHEC resources
  - https://scdhec.gov/health/inf ectious-diseases/hiv-stdviral-hepatitis/pre-exposureprophylaxis-prep



#### Why PrEP?

South Carolina has one of the highest HIV rates in the US.

PrEP is a highly effective biomedical method of preventing an uninfected person from acquiring HIV. Goal: Increase the use of PrEP to prevent HIV infection. Mission
Calendar
Resources/Links
Faculty

#### Contact U

SC HIV PrEP Telehealth Initiative Program

University of SC School of Medicine

One Richland Medical Park
Suite 320
Columbia, SC 29203

Columbia, SC 29203 To arrange for provider education, please call: 803-545-5402

http://schivtc.med.sc.edu/

Services: PrEP Clinic

Immunology Center One Richland Medical Park Suite 420

Columbia, SC 29203 To make an appointment, please call: 803-545-5350



ome \ Health \ Infectious Diseases \ HIV, STD, & Viral Hepatitis \ Current Page

Pre-Exposure Prophylaxis (PrEP)



PrEP is a pill (Truvada) that can be taken once a day to greatly reduce your chances of getting HIV if exposed to the virus. If taken as directed PrEP can reduce your risk of getting HIV by more than 90%.

PrEP WILL NOT protect you from STIs, like syphilis, gonorrhea, or chlamydia, so using a condom while on PrEP is advised.

months to undergo screenings to ensure a negative result and assess any other issues related to Truvada's side effects. All though side effects are minimum, the provider should monitor the patier throughout the time the patient is taking Truvada.

- Taking PFEP once a day has shown to reduce the risk of getting HIV from sex by more than 90%.
   Daily PFEP use can also reduce HIV among individuals who inject drugs by more than 70%.
   In clinical trails some individuals expendenced each side fifters like an upper stomach colors of
- In clinical trials, some individuals experienced early side effects like an upset stomach or loss of appetite. These side effects were mild and went away within the first month. During the study, no serious side effect was observed.
- The CDC recommends PrEP for individuals who are HIV negative who may be at risk of being exposed. You should contact your medical provider if you are at risk for HIV.



Downloads & Links

PrEP Provider Locate

SC PrEP Providers

PrEP 101 (pdf)

Prep FAQs (pdf)

PrEP Patient Assistance









# PrEP and Insurance Coverage



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