



**California State Board of Pharmacy**

2720 Gateway Oaks Drive, Ste 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency

Department of Consumer Affairs

Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IV. Discussion and Consideration for Board Approval of Proposed Board Provided Training Program Pursuant to Business and Professions Code sections 4052.02(b), 4052.03(b)(3) Related to Furnishing HIV Preexposure (PrEP) and Postexposure (PEP) Prophylaxis

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Relevant Law

BPC 4052.02 provides the authority for a pharmacist to initiate and furnish HIV preexposure prophylaxis under specified conditions, including completion of a training program.

BPC 4052.03 provides the authority for a pharmacist to initiate and furnish HIV postexposure prophylaxis under specified conditions, including completion of a training program

California Code of Regulation (CCR) section 1747 establishes, via emergency regulation, the requirements to the training program required in the relevant underlying statute.

Background

As part of the Board's efforts to implement the provisions of SB 159, Board staff in collaboration with experts have been developing a training program to satisfy the requirements of CCR section 1747. Ultimately, upon approval by the Board, the training program will be finalized, and a competency assessment and post training survey developed. Once finalized, the training program will be recorded and made available on the Board's website at no cost to licensees.

The experts involved in the development of this training program include:

- Phillip Peters, MD, Office of AIDS Medical Director
- Marisa Ramos, Ph.D, Office of AIDS Division Chief
- Kirsten B. Balano, PharmD, AAHIVP (HIV-Pharmacist)
- James Gaspar, PharmD, BCPP, Psychiatric and Substance Use Disorder Pharmacist

For Board Discussion and Consideration

During the meeting members will have the opportunity to receive a brief overview of the training program as well as discuss the draft PowerPoint presentation. As indicated in the PowerPoint, the training will consist of several modules and conclude with two case studies. Below is a brief description of the content areas and learning objectives:

**Role of Pharmacists in HIV Prevention**

Learning Objectives

1. Describe the HIV Care Continuum to measure "Getting to Zero" Goals.

2. Identify 4 HIV prevention tools available to California Pharmacists.

### **PrEP Basics (CCR Section 1747(a)(1)(A)-(D),(F))**

#### Learning Objectives

1. Describe data supporting the use of PrEP in HIV prevention.
2. Use CDC Guidelines to identify patients appropriate for starting PrEP medications.
3. Counsel patients regarding the importance of confirming negative HIV test prior to starting HIV PrEP.
4. Counsel patients regarding dosing and common-side effects for PrEP medications.
5. Consider patients appropriate for tenofovir diproxil fumerate versus tenofovir alafenamide containing PrEP regimens.
6. Counsel patients regarding linkage to care and follow-up laboratory monitoring.

### **PEP Basics (CCR Section 1747(a)(1)(A)-(D),(F))**

#### Learning Objectives:

1. Identify patients who can benefit from post-exposure prophylaxis (PEP) for HIV.
2. Choose a PEP regime appropriate for the patient.
3. Effective counsel patients about the risk of HIV infection after exposure and benefit of PEP.
4. Link patients to care for follow-up testing and support following HIV exposure.

### **Legal Requirements (CCR Section 1747(a)(1)(B))**

Learning Objective: Define key aspects of legislation authorizing pharmacists to furnish PrEP and PEP in California.

### **HIV Testing (CCR Section 1747(a)(1)(D))**

#### Learning Objectives:

1. Determine recommended HIV test based on clinical circumstances.
2. Identify pathway for testing outside traditional settings.

### **Patient Financial Considerations (CCR Section 1747(a)(1)(E))**

Learning Objective: Distinguish reimbursement resources for insured and uninsured individuals.

### **Case studies**

Learning Objectives: Apply knowledge through a PrEP case study and a PEP case study.

### **Recommendation**



Recommendation

Board staff recommend approval of the training program. Should members agree with staff's recommendation, the following motion could be used to facilitate approve.

SUGGESTED MOTION: Approve the Proposed Board Provided Training Program Pursuant to Business and Professions Code sections 4052.02(b), 4052.03(b)(3) Related to Furnishing HIV Preexposure (PrEP) and Postexposure (PEP) Prophylaxis

Following this memo is a copy of the relevant law, biographies of experts, and the training PowerPoint.

## ***Relevant Law***

**State of California**

**BUSINESS AND PROFESSIONS CODE**

**Section 4052.02**

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4052.02. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “preexposure prophylaxis” means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, “CDC guidelines” means the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist’s satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.



STATE OF CALIFORNIA  
**AUTHENTICATED**  
ELECTRONIC LEGAL MATERIAL

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

(Added by Stats. 2019, Ch. 532, Sec. 2. (SB 159) Effective January 1, 2020.)

**State of California**

**BUSINESS AND PROFESSIONS CODE**

**Section 4052.03**

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4052.03. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “postexposure prophylaxis” means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, “CDC guidelines” means the “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for

postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

(Added by Stats. 2019, Ch. 532, Sec. 3. (SB 159) Effective January 1, 2020.)

**Title 16. Board of Pharmacy  
Proposed Text**

***Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:***

**§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.**

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(D) Patient referral resources and supplemental resources for pharmacists.

(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).

(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code.  
Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

# ***Expert Biographies***



## BIOGRAPHIC SKETCH

Phil Peters is a Medical Officer in OA who works to improve HIV prevention programs and medical care for people living with HIV in California. Phil believes that public health works best when it partners with both community groups and medical providers. At OA, Phil has worked to help expand HIV pre-exposure prophylaxis options and has evaluated how molecular information can be used to help improve HIV prevention. He also chairs the medical advisory committee for California's ADAP and the clinical quality management committee for California's Ryan White Part B program. During the COVID-19 pandemic, he has been helping CDPH's clinical team investigate this new illness and options for prevention that can be applied in the community.

Prior to joining OA in November 2018, Phil worked for the Centers for Disease Control and Prevention (CDC) and in this position he led CDC's field investigation team during the largest US HIV outbreak in 20 years, which occurred among people who inject drugs in a rural community. This response interrupted further HIV transmission in the community and resulted in significant federal public health policy changes related to injection drug use.

Phil is board certified in infectious disease medicine and is a volunteer clinical faculty member at the University of California at Davis's department of infectious disease. Phil is also a member of the immunization panel for the US "Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents".

Marisa Ramos, PhD, has been with the California Department of Public Health for 11 years. Currently, she is the Office of AIDS (OA) Chief. Previously she served as the OA as the Surveillance and Prevention Evaluation and Reporting Branch Chief for Office of AIDS. She has 25 years of experience managing research projects, data systems, and surveillance efforts, and has authored publications and presented at local, state, national and international conferences on refugee and Latino health issues. Prior to coming to CDPH, Dr. Ramos was an Adjunct Professor of Biology at the University of California, Davis, where she currently serves as a volunteer Professor of Public Health. Dr. Ramos completed both Masters and Doctoral programs in Biological Nutrition with an emphasis in Epidemiology from the University of California, Davis.

***James J. Gasper, PharmD, BCPP.*** Dr. Gasper received his Doctorate of Pharmacy from the University of Colorado. He completed his pharmacy practice residency at the Denver Veterans Affairs Medical Center and psychiatric pharmacy residency at the University of California San Francisco. Following residency training Dr. Gasper spent almost 10 years in a Ryan White funded HIV prevention program for MSM with methamphetamine use disorder in San Francisco. In his current capacity Dr. Gasper serves as a psychiatric and substance use disorder pharmacist for the Department of Health Care Services and a substance use specialist for the UCSF Clinician Consultation Center Substance Abuse Warmline.

# ***Draft Training PowerPoint Presentation***

# DRAFT

## HIV PRE-EXPOSURE AND POST-EXPOSURE PROPHYLAXIS FOR CALIFORNIA PHARMACISTS

FIRST & LAST NAME

TITLE

DATE



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# OVERVIEW

- ROLE OF PHARMACISTS IN HIV PREVENTION
- PREP BASICS
- PEP BASICS
- LEGAL REQUIREMENTS OF FURNISHING IN CALIFORNIA
- HIV TESTING
- PATIENT FINANCIAL CONSIDERATIONS
- CASES
  - PREP
  - PEP





# LEARNING OBJECTIVES

- DESCRIBE THE HIV CARE CONTINUUM TO MEASURE “GETTING TO ZERO” GOALS.
- IDENTIFY 4 HIV PREVENTION TOOLS AVAILABLE TO CALIFORNIA PHARMACISTS





# HIV CARE CONTINUUM

## HIV CARE CONTINUUM:

The series of steps a person with HIV takes from diagnosis through their successful treatment with HIV medication.





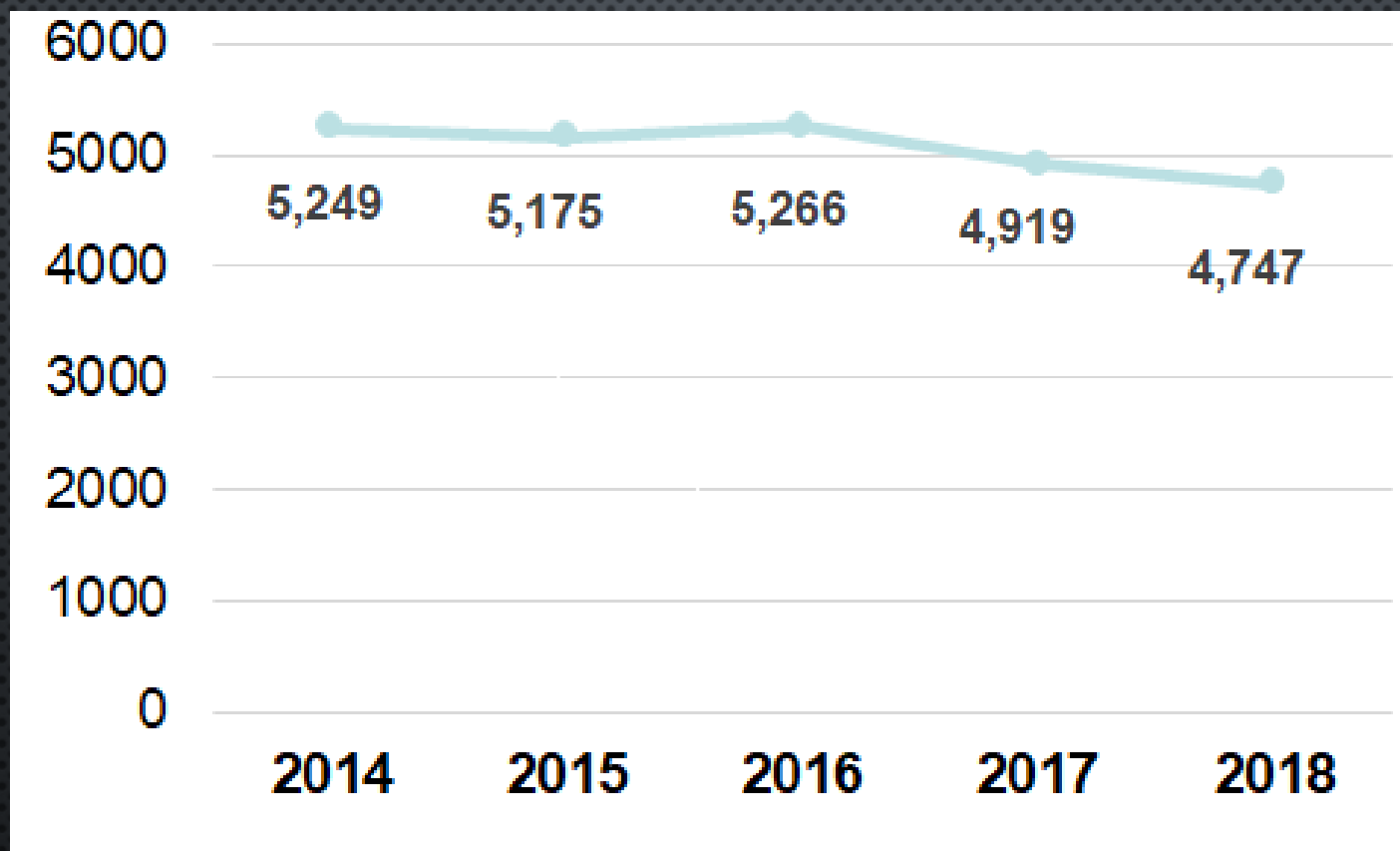
# HIV PREVENTION BY PHARMACISTS

- TO ADDRESS HIV PREVENTION, WHICH IS THE PATIENTS PRIOR TO DIAGNOSIS, YET AT RISK FOR HIV INFECTION.
- PHARMACISTS ARE A SOURCE OF SIGNIFICANT HIV PREVENTION AND HARM REDUCTION:
  - CONDOMS
  - STERILE SYRINGES
  - TREATMENT AS PREVENTION: UNDETECTABLE = UNTRANSMITTABLE
  - NALOXONE
- SKILLS FOR THESE SERVICES ARE SIMILAR TO OTHER PUBLIC HEALTH PREVENTION INTERVENTIONS AVAILABLE BY PHARMACISTS:
  - BIRTH CONTROL
  - IMMUNIZATIONS
  - TOBACCO CESSATION



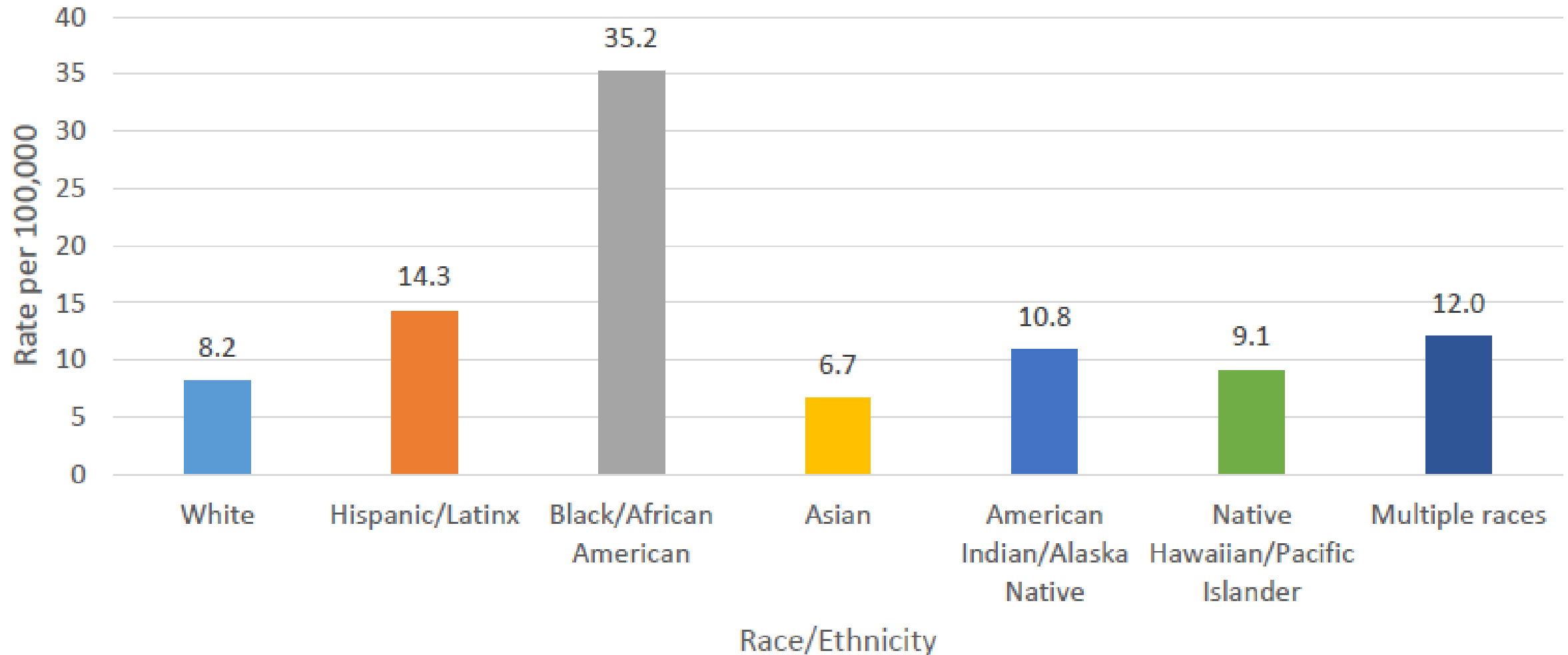


## PEOPLE DIAGNOSED WITH HIV INFECTION IN CALIFORNIA, 2014 – 2018



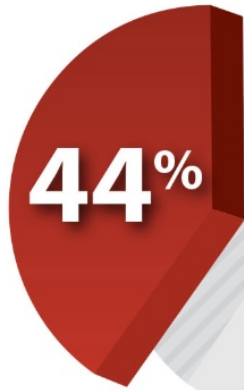
California Department of Public Health, Office of  
AIDS, California  
HIV Surveillance Report — 2018.

## RATE OF NEWLY DIAGNOSED HIV BY RACE/ETHNICITY –CALIFORNIA, 2017





# HIV prevention pill is not reaching most who could potentially benefit – especially African Americans and Latinos



of people who could potentially benefit from PrEP are **African American** – **approximately 500,000 people...**

...but only **1%** of those – **7,000 African Americans** – were prescribed PrEP\*



of people who could potentially benefit from PrEP are **Latino** – **nearly 300,000 people...**

...but only **3%** of those – **7,600 Latinos** – were prescribed PrEP\*



\*Prescription data in this analysis limited to those filled at retail pharmacies or mail order services from September 2015 – August 2016; racial and ethnic information not available for one-third of the prescription data





# POST-EXPOSURE PROPHYLAXIS (PEP)

- EMERGENCY ACCESS TO HIV TREATMENT REGIMENS STARTED AS SOON AS POSSIBLE AFTER EXPOSURE TO HIV – (WITHIN 72 HOURS)
- GUIDELINES FOR USE IN OCCUPATIONAL AND NON-OCCUPATIONAL SETTINGS
- CAN REDUCE RISK OF TRANSMISSION FROM EXPOSURE BY 80%
- 28 DAY TREATMENT COURSE





# SB 159: NEW HIV PREVENTION TOOL

- ALLOWS PHARMACISTS TO FURNISH HIV PREVENTION MEDICATIONS FOR 30 – 60 DAYS.
- REQUIRES PHARMACISTS SUPPORT PATIENTS LINKAGE TO CARE FOR CONTINUOUS PREVENTION PRESCRIPTIONS
- IMPROVES HIV PREVENTION ACCESS POINTS FOR PATIENTS





# ROLE OF PHARMACISTS IN PREP AND PEP

- BY INCREASING THE ACCESS TO PREP MEDICATIONS, CAN IMPROVE HIV PREVENTION FOR THOSE AT RISK.
- PHARMACISTS HAVE RELATIONSHIPS WITH PRESCRIBERS AND CAN LINK PATIENTS TO CARE FOR ON-GOING PRESCRIPTIONS
- EMERGENCY POST-EXPOSURE PROPHYLAXIS IS TIME-SENSITIVE FOR EFFICACY AND PHARMACIES UNIQUELY SITUATED FOR EMERGENCY ACCESS
  - SIMILAR TO EMERGENCY CONTRACEPTION ACCESS





# SUMMARY

- PHARMACISTS HAVE PLAYED AN IMPORTANT ROLE IN HIV PREVENTION FOR DECADES, WITH ACCESS TO CONDOMS, STERILE SYRINGES AND SUPPORTING ADHERENCE TO HIV TREATMENT.
- PHARMACISTS ARE UNIQUELY SITUATED TO IMPROVE ACCESS TO NEW PREVENTION TOOLS, PREP AND PEP, ESPECIALLY FOR PATIENTS WHO ARE UNDERSERVED.
- PHARMACISTS HAVE RELATIONSHIPS WITH PRESCRIBERS AND CAN SUPPORT LINKAGE TO CARE FOR ONGOING PREP PRESCRIPTIONS, HIV TESTING AND LAB MONITORING.





# PRE-EXPOSURE PROPHYLAXIS (PREP)



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# LEARNING OBJECTIVES

- DESCRIBE THE DATA SUPPORTING USE OF PrEP IN HIV PREVENTION
- USE CDC GUIDELINES TO IDENTIFY PATIENTS APPROPRIATE FOR STARTING PrEP MEDICATIONS.
- COUNSEL PATIENTS REGARDING THE IMPORTANCE OF CONFIRMING NEGATIVE HIV TEST PRIOR TO STARTING HIV PrEP.
- COUNSEL PATIENTS REGARDING DOSING AND COMMON SIDE-EFFECTS FOR PrEP MEDICATIONS.
- CONSIDER PATIENTS APPROPRIATE FOR TENOFOVIR DIPROXIL FUMERATE VERSUS TENOFOVIR ALAFENAMIDE CONTAINING PrEP REGIMENS.
- COUNSEL PATIENTS REGARDING LINKAGE TO CARE AND FOLLOW-UP LABORATORY MONITORING.





# WHAT IS PREP?

- PREP IS A FIXED-DOSE COMBINATION OF TWO ANTIVIRAL MEDICATIONS WITH ACTIVITY AGAINST HIV THAT PATIENTS WITHOUT HIV INFECTION CAN TAKE DAILY TO PREVENT INFECTION.
- TENOFOVIR DIPROXIL FUMERATE (DF) 300MG AND EMTRICITABINE 200MG ARE COMBINED IN THE BRAND NAME PRODUCT TRUVADA.
- TENOFOVIR ALAFENAMIDE (AF) 25MG AND EMTRICITABINE 200MG ARE COMBINED IN THE BRAND NAME PRODUCT DESCOVY.
- DATA FROM STUDIES SUGGEST PREP IS SAFE AND ABLE TO REDUCE HIV INFECTIONS BY ABOUT 99% WHEN TAKEN DAILY.





# PHARMACOLOGY

- TENOFOVIR (BOTH THE DF AND AF FORMULATIONS) AND EMTRICITABINE ARE BOTH NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS.
- THEY CAN PREVENT HIV INFECTION FROM ESTABLISHING BY BLOCKING HIV REVERSE TRANSCRIPTASE ENZYME FROM CREATING INTRACELLULAR VIRAL DNA.
- THESE MEDICATIONS ARE ALSO USED IN COMBINATION WITH A THIRD MEDICATION TO TREAT PEOPLE LIVING WITH HIV INFECTION.
- PREP – TWO DRUG NRTI THERAPY – SHOULD NEVER BE USED FOR PEOPLE INFECTED WITH HIV.
- PREP CAN ONLY BE USED FOR THOSE INDIVIDUALS WHO HAVE DOCUMENTED NEGATIVE HIV TEST (WITHIN 7 DAYS OF PREP START).



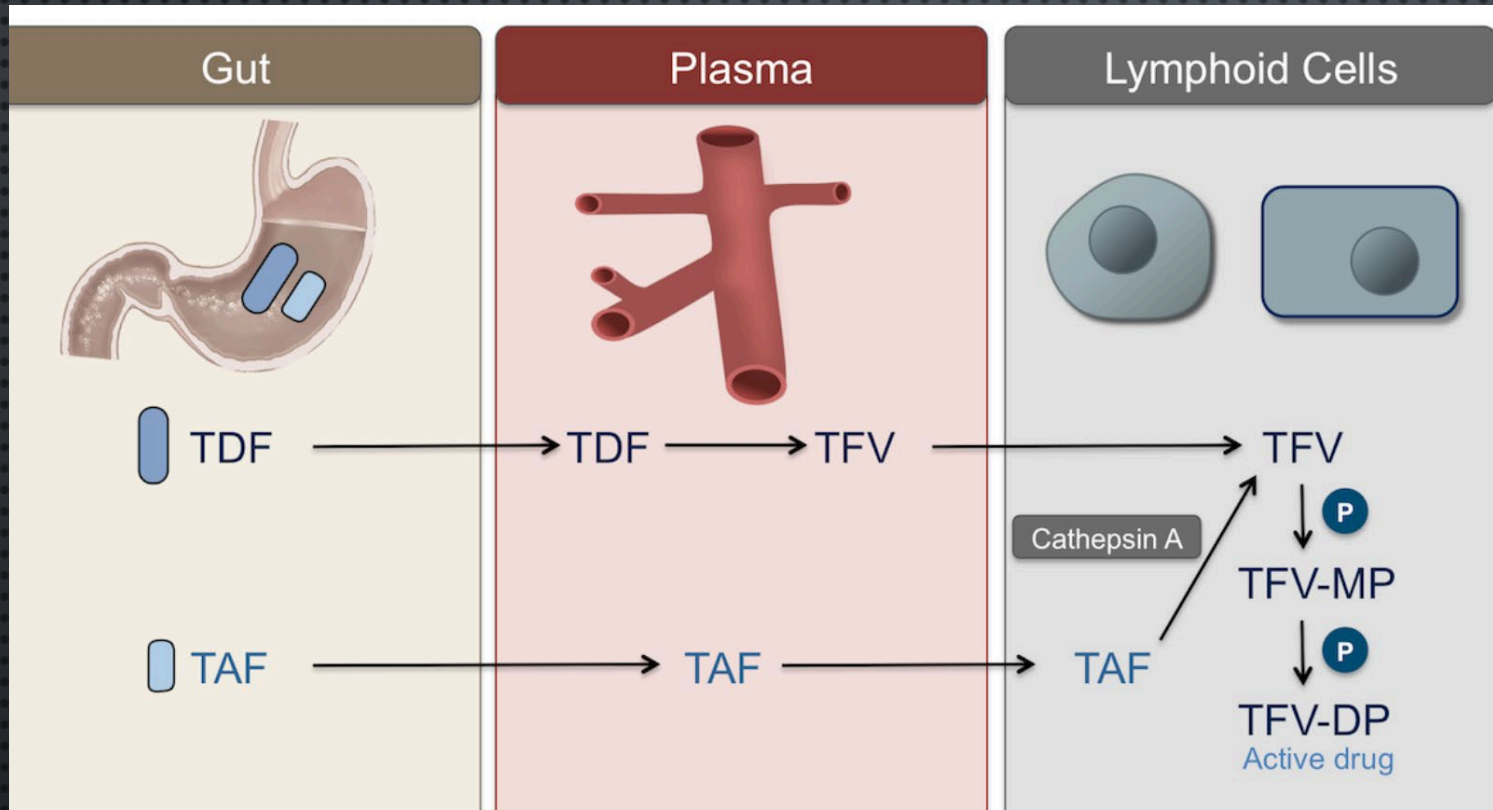


# PHARMACOLOGY (CONT)

- THE MEDICATIONS USED FOR PREP ARE ALSO ACTIVE AGAINST HEPATITIS B VIRUS (HBV).
- PATIENTS STARTED ON PREP NEED TO HAVE A HEPATITIS B SCREENING AS PART OF BASELINE LABORATORY MONITORING.
- PATIENTS WHO ARE CHRONICALLY INFECTED WITH HBV NEED TO BE COUNSELED NOT TO STOP PREP UNLESS ADVISED BY THEIR PRIMARY CARE PROVIDER.
  - ABRUPT DISCONTINUATION OF PREP FOR PATIENTS CHRONICALLY INFECTED WITH HBV CAN CAUSE HBV FLARES AND SIGNIFICANT MORBIDITY.







TDF = tenofovir disoproxil fumarate; TFV = tenofovir; MP = monophosphate; DP = diphosphate

Figure 4 - Metabolism of Tenofovir DF and Tenofovir alafenamide

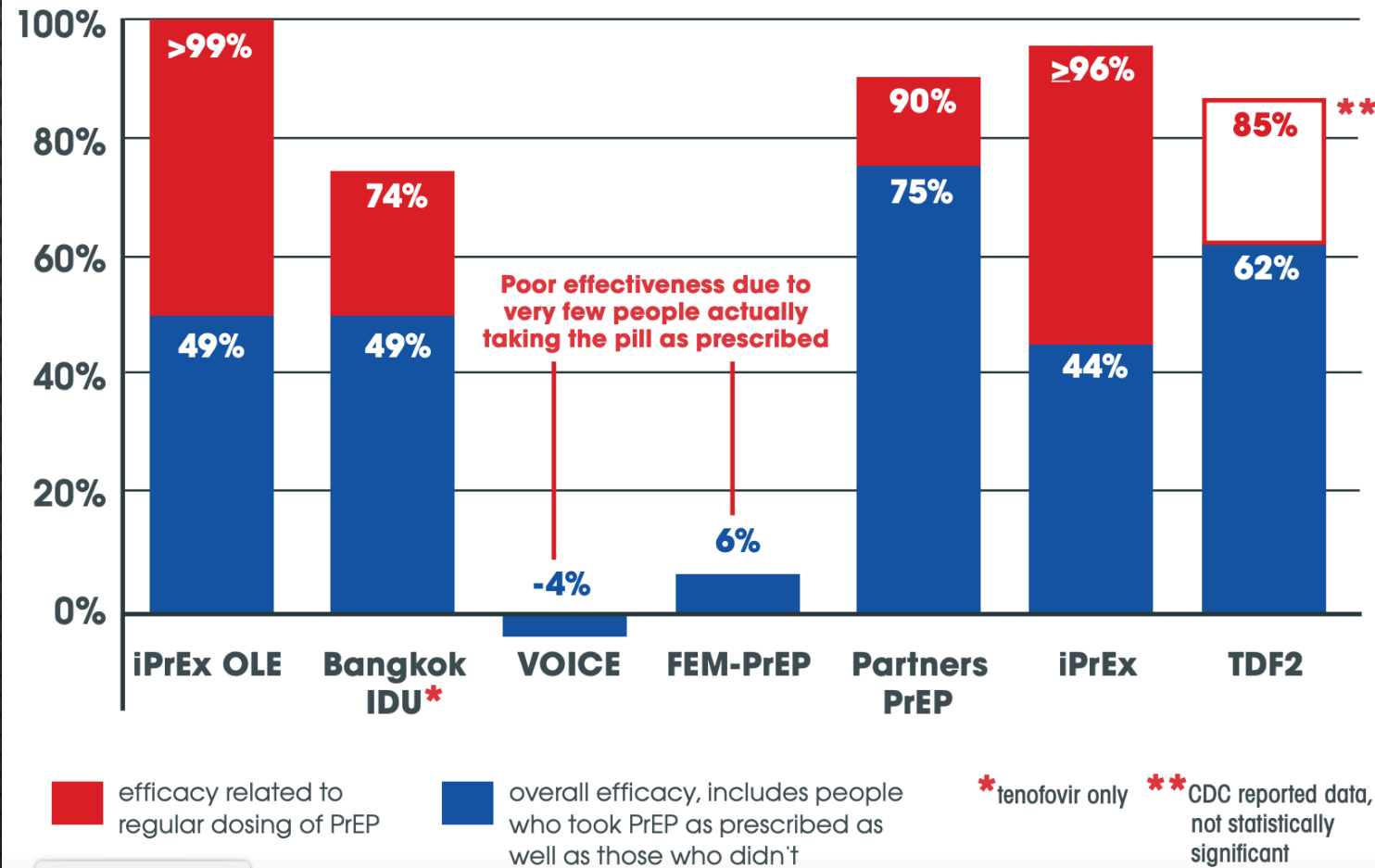
A 15 mg dose of tenofovir alafenamide has 90% lower circulating plasma tenofovir levels when compared with a 300 mg dose of tenofovir

# PHARMACOLOGY TAF VS TDF



From National HIV Curriculum Slide Deck

# CLINICAL TRIALS FOR PREP AS PREVENTION





# PREP EFFICACY

- PREP IS 99% EFFECTIVE WITH GOOD ADHERENCE
- DISCOVER TRIAL DEMONSTRATED TAF/EMTRICITABINE NON-INFERIOR TO TDF/EMTRICITABINE FOR PREP IN MSM.
  - SIDE-EFFECT PROFILE DIFFERENCES: LESS RENAL AND BONE EFFECTS IN TAF GROUP
  - SUBSEQUENT TRIALS SUGGEST MORE WEIGHT GAIN AND CHOLESTEROL INCREASES WITH TAF VS TDF.
  - TAF NOT STUDIED IN PREP EFFECTIVENESS IN WOMEN.





# WHO MAY BENEFIT FROM PREP?

HIV-NEGATIVE INDIVIDUALS, INCLUDING ADOLESCENTS, MEN WHO HAVE SEX WITH MEN, CIS- AND TRANSGENDER WOMEN, INCLUDING:

- ANYONE WHO REQUESTS PREP
- PEOPLE WITH SEXUAL EXPOSURES INCLUDING: CONDOMLESS ANAL SEX, MULTIPLE SEX PARTNERS AT HIGH RISK FOR HIV, OR TRANSACTIONAL SEX (I.E SEX FOR MONEY, DRUGS OR HOUSING)
- PEOPLE WHO INJECT DRUG AND PEOPLE WHO USE STIMULANTS, SUCH AS METHAMPHETAMINE, DURING SEX
- PEOPLE WHO HAVE PARTNERS LIVING WITH HIV
- PEOPLE WHO HAVE HAD BACTERIAL SEXUALLY TRANSMITTED INFECTION (STI)

CRITICAL TO CONFIRM HIV NEGATIVE STATUS PRIOR TO STARTING PREP (WITHIN 7 DAYS)

PREP REGIMENS ARE NOT COMPLETE REGIMENS FOR HIV TREATMENT AND CAN INDUCE DRUG RESISTANCE IF TAKEN BY PEOPLE LIVING WITH HIV INFECTION(PLWH)





# PREP DOSING

- TENOFOVIR DF 300MG + EMTRICITABINE 200MG (TRUVADA) ONE TABLET DAILY
  - NOT RECOMMENDED IF CLCR < 60 ML/MIN
  - INTERMITTENT/ON-DEMAND DOSING STRATEGIES HAVE SOME EFFICACY, NOT CURRENTLY INCLUDED IN CDC GUIDELINES
- TENOFOVIR AF 25MG + EMTRICITABINE 200MG (DESCOVY) ONE TABLET DAILY
  - NOT RECOMMENDED FOR PEOPLE ASSIGNED FEMALE AT BIRTH OR WITH HIV EXPOSURES VIA VAGINAL SEX.
  - NOT RECOMMENDED IF CLCR < 30 ML/MIN
  - NOT RECOMMENDED FOR PEOPLE ALSO USING RIFAMPIN





# HOW TO CHOOSE TDF VS TAF?

TDF HAS MOST DATA SUPPORTING EFFICACY AND EXPERIENCE IN USE. BOTH AGENTS ARE HIGHLY EFFECTIVE AND SAFE. TDF-RELATED TOXICITIES, WHICH ARE GENERALLY RARE, HAVE BEEN OBSERVED AFTER MONTHS – YEARS ON MEDICATION. SO FOR THE 30 – 60 DAY DURATION OF SB159 PREP FURNISHING, TDF WILL BE SAFE FOR THE VAST MAJORITY OF PATIENTS. ONCE LINKED TO CARE AND FURTHER BASELINE TESTING COMPLETED, PROVIDERS CAN ADJUST PRESCRIPTION IF NEEDED.

AGE: >50 YEARS TAF MAY BE SAFER OPTION

GENDER: FEMALE AT BIRTH TDF IS APPROPRIATE

CO-MORBID CONDITIONS: DM, HTN, RENAL DYSFUNCTION, OSTEOPOROSIS – TAF MAY BE SAFER OPTION

DRUG INTERACTIONS: RIFAMPIN – TDF HAS LESS DRUG-DRUG INTERACTIONS





# TIME TO MAXIMUM PROTECTION

- ABOUT 7 DAYS IN RECTAL MUCOSA
- ABOUT 21 DAYS IN CERVICO-VAGINAL TISSUE
- ABOUT 21 DAYS IN BLOOD (IDU)





# ADVERSE EFFECTS

- PREP DOES NOT PREVENT OTHER STI
  - MONITOR PATIENTS WITH FOR GONORRHEA AND CHLAMYDIA – AT SITES APPROPRIATE FOR SEXUAL ACTIVITY: 3 SITES RECOMMENDED: URINE, RECTAL SWABS, THROAT SWABS.
  - MONITOR FOR SYPHILIS WITH RPR
  - MONITOR FOR HEPATITIS C YEARLY
  - MONITOR FOR HEPATITIS B AT BASELINE
    - BECAUSE PREP MEDICATIONS ALSO HAVE ACTIVITY AGAINST HBV, PATIENTS LIVING WITH HBV NEED TO BE COUNSELED NOT TO STOP PREP AS ABRUPT DISCONTINUATION CAN CAUSE HBV FLARE.
- SELF-LIMITING EFFECTS: NAUSEA, DIARRHEA, FLATULENCE, HEADACHES
  - GENERALLY RESOLVE WITHIN 1-2 WEEKS
  - CAN MITIGATE WITH USE OF GINGER FOR NAUSEA, TAKE WITH FOOD, DIETARY ADJUSTMENTS FOR DIARRHEA AND FLATULENCE, NSAIDS OR APAP FOR HEADACHES
- RARELY, MORE SEVERE SIDE EFFECTS OF RENAL DYSFUNCTION AND OSTEOPOROSIS
  - IN STUDIES, PATIENTS > 50 YO AT HIGHER RISK FOR RENAL AND BONE TOXICITIES





# WORKFLOW FOR PREP

- IDENTIFY PATIENT WHO WILL BENEFIT FROM PREP
- CONFIRM HIV NEGATIVE STATUS AND NO SIGNS OF ACUTE HIV INFECTION
  - PERFORM HIV ANTIGEN/ANTIBODY TEST OR PATIENT BRINGS HIV TEST RESULT FROM W/IN 7 DAYS OF START
- COUNSEL ON IMPORTANCE OF DAILY ADHERENCE, OFFER ADHERENCE SUPPORT (I.E. PHONE APP) AND NEED TO LINK TO PRESCRIBER FOR LABORATORY ASSESSMENT (STI, HBV, RENAL FXN) AND ONGOING PRESCRIPTIONS.
  - PLEASEPREPME.ORG OR LOCAL DPH WITH LIST OF PREP PROVIDERS IN AREA
- DISPENSE 30D PREP
  - ENROLL IN PATIENT ASSISTANCE PROGRAM FOR COPAY SUPPORT OR UNINSURED
- BILL MEDICAL FOR COUNSELING SERVICES
- AT 30 DAY REFILL, CONFIRM LINKAGE TO CARE, ASSESS ADHERENCE
- CAN DISPENSE ANOTHER 30 DAY SUPPLY OF PREP FOR PATIENTS WITH GOOD ADHERENCE AND COMMITMENT TO LINK TO CARE





# ADOLESCENT CONSIDERATIONS

- TDF/EMTRICITABINE (TRUVADA) IS FDA APPROVED FOR HIV PREVENTION FOR ADULTS AND ADOLESCENTS WEIGHING AT LEAST 35 KG.
- COUNSELING AT RISK ADOLESCENTS WILL INCLUDE AN ASSESSMENT FOR PRIVACY AND INSURANCE BILLING REPORTS.
  - PHARMACISTS ARE FAMILIAR WITH THESE ISSUES FOR ADOLESCENTS RECEIVING BIRTH CONTROL.





# SUMMARY

- PHARMACISTS HAVE THE TRAINING AND EXPERTISE TO SUPPORT PATIENTS WHO WOULD BENEFIT FROM PREP.
- PHARMACISTS HAVE THE SKILLS TO COUNSEL PATIENTS ABOUT THE IMPORTANCE OF ADHERENCE AND LINKAGE TO CARE.
  - IDENTIFY AND COLLABORATE WITH PREP PROVIDERS IN YOUR AREA
- CONFIRM HIV NEGATIVE STATUS IS CRITICAL BEFORE STARTING PREP
  - IDENTIFY HIV TESTING PROGRAMS AND ABILITY TO PROVIDE CLIA-WAIVED TESTS IN YOUR AREA.
- PATIENTS NEED TO BE LINKED TO CARE FOR LABORATORY MONITORING OF STI, RENAL FUNCTION AND HBV STATUS AS WELL AS ON-GOING PRESCRIPTIONS.





# POST-EXPOSURE PROPHYLAXIS (PEP)



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# LEARNING OBJECTIVES

- IDENTIFY PATIENTS WHO CAN BENEFIT FROM POST-EXPOSURE PROPHYLAXIS (PEP) FOR HIV
- CHOOSE A PEP REGIMEN APPROPRIATE FOR THIS PATIENT
- EFFECTIVELY COUNSEL PATIENTS ABOUT THE RISK OF HIV INFECTION AFTER EXPOSURE AND BENEFIT OF PEP
- LINK PATIENTS TO CARE FOR FOLLOW-UP TESTING AND SUPPORT FOLLOWING HIV EXPOSURE.





# ASSESS RISK FOR HIV BASED ON EXPOSURE < 72HRS

Level of risk	Types of exposures
<b>High risk ► offer PEP</b>	<ul style="list-style-type: none"><li>• Condomless receptive anal sex</li><li>• Condomless receptive vaginal sex</li><li>• Sharing needles</li></ul>
<b>Moderate risk ► consider PEP, discuss with patient</b>	<ul style="list-style-type: none"><li>• Condomless insertive anal sex</li><li>• Condomless insertive vaginal sex</li></ul>
<b>Low risk ► would not offer PEP</b>	<ul style="list-style-type: none"><li>• Insertive or receptive oral sex (consider for receptive if significant bleeding, ulcerations or trauma in mouth and ejaculation)</li><li>• Sharing cookers, cotton or other drug paraphernalia</li><li>• Blood or semen splash on intact skin</li><li>• Exposure to urine</li></ul>





# ASSESS FOR ACUTE HIV SYMPTOMS

- CURRENT HIGH FEVER
- FATIGUE
- SORE THROAT/PHARYNGITIS
- RASH
- LYMPHADENOPATHY

PATIENTS WITH THESE SYMPTOMS NEED TO BE REFERRED TO CARE FOR HIV RNA TESTING AND SUPPORTIVE CARE. PROVIDE CONDOMS AS PATIENTS ARE INFECTIOUS FOR HIV TRANSMISSION DURING ACUTE PHASE OF INFECTION.





# CHOOSE A REGIMEN FOR 28 DAY TREATMENT COURSE

STUDIES OF OCCUPATIONAL PEP SUGGEST USE OF EFFECTIVE HIV TREATMENT REGIMENS ASAP AFTER HIV EXPOSURE CAN REDUCE RISK OF HIV INFECTION BY 80%

- 1) BICTEGRAVIR/TENOFOVIR ALAFENAMIDE/EMTRICITABINE (BIKTARVY) ONE PILL ONCE/DAY
- 2) TENOFOVIR DF 300MG/EMTRICITABINE 200MG (TRUVADA) + DOLUTEGRAVIR 50MG (TIVICAY) ONE TABLET EACH ONCE DAILY
- 3) TENOFOVIR DF 300MG/EMTRICITABINE 200MG (TRUVADA) ONE TABLET DAILY + RALTEGRAVIR 600MG (ISENTRESS) TWO TABLETS DAILY OR RALTEGRAVIR 400MG ONE TABLET TWICE DAILY

FOR PATIENTS AT RISK FOR  $CLCr < 60$  ML/MIN CAN REPLACE TENOFOVIR DF WITH TENOFOVIR ALAFENAMIDE/EMTRICITABINE (DESCOVY).

DOLUTEGRAVIR CAN INCREASE METFORMIN LEVELS AND SHOULD NOT BE USED FOR PATIENTS TAKING  $> 1000$ MG/DAY METFORMIN.





# ALTERNATIVE PEP REGIMENS

- ELVITEGRAVIR/COBICISTAT/TENOFOVIR DF OR TAF/EMTRICITABINE (STRIBILD OR GENVOYA) ONE TABLET DAILY
- TENOFOVIR DF/EMTRICITABINE (TRUVADA) + DARUNAVIR/COBICISTAT (PREZCOBIX) OR DARUNAVIR 600MG (PREZISTA) + RITONAVIR 100MG (NORVIR) ONE TABLET EACH ONCE DAILY.

THESE REGIMENS CONTAIN PHARMACOKINETIC BOOSTERS (COBICISTAT AND RITONAVIR) WHICH CAN INTERACT WITH OTHER MEDICATIONS THAT ARE SUBSTRATES OR METABOLIZED BY CYP3A4 ISOENZYMES (I.E. FLUTICASONE, ED AGENTS, STATINS, ANTIDEPRESSANTS, ANTISEIZURE MEDICATIONS). APPROPRIATE FOR PATIENTS NOT TAKING MEDICATIONS AT RISK FOR DRUG-DRUG INTERACTIONS.





# COUNSEL PATIENTS FOR SUPPORTIVE CARE

- LINK PATIENTS TO PROVIDER TO PROVIDE F/U HIV, HBV, HCV AND STI TESTING.
- PATIENTS WILL NEED BOTH BASELINE TESTING ALONG WITH REPEAT HIV TESTING FOLLOWING 28 DAY PEP REGIMEN.
- COUNSEL PATIENTS ABOUT COMMON SIDE-EFFECTS: PEP REGIMENS CAN CAUSE NAUSEA, BLOATING, DIARRHEA, FLATULENCE, HEADACHES – OFTEN SELF-LIMITING
  - CAN MITIGATE EFFECTS BY TAKING WITH FOOD, USING GINGER-CONTAINING FOOD/BEVERAGES, ADJUST DIET AND NSAIDS OR APAP FOR HEADACHES.
- COUNSEL TO SUPPORT ADHERENCE: PILL BOX, ALARM, PHONE REMINDER APPS, CONNECT TO DAILY ROUTINE





# PEP WORKFLOW

- ELICIT EXPOSURE HISTORY FOR TIMING (<72 HRS) AND ASSESS RISK OF HIV TRANSMISSION
- ASSESS FOR ACUTE HIV SYMPTOMS
- FOR HIGH OR MODERATE RISK EXPOSURES IN PATIENTS WITHOUT ACUTE SYMPTOMS, COUNSEL PATIENT REGARDING BENEFIT OF PEP
- CHOOSE AND DISPENSE 30D SUPPLY OF APPROPRIATE PEP REGIMEN – STARTING COMPLETE PEP ASAP AFTER EXPOSURE IMPROVES EFFICACY, DO NOT DELAY PEP TO ORDER MEDICATION.
  - ACCESS PATIENT ASSISTANCE PROGRAMS FOR UNINSURED OR COPAY ASSISTANCE
- COUNSEL PATIENT ON NEED TO LINK TO CARE FOR LABORATORY TESTING
- COUNSEL PATIENT REGARDING ADHERENCE AND SIDE-EFFECT MANAGEMENT
- CONSIDER COUNSELING PEP TO PREP FOR PATIENTS WHO CAN BENEFIT FROM PREP





# PEDIATRIC CONSIDERATIONS

- PEP IN CHILDREN HAS PRIMARILY BEEN CONSIDERED DURING SEXUAL ASSAULT SITUATIONS
- ARV USE IN PEDIATRICS CAN NEED DOSE ADJUSTMENTS, AND THESE DOSES ARE AVAILABLE IN PEDIATRIC ARV GUIDELINES.
- THESE DOSES ARE NOT INCLUDED IN LEGISLATION UNDER SB159 CURRENTLY
  - CAN REFER TO EMERGENCY ROOM, WHO ALSO HAVE SEXUAL ASSAULT SUPPORT SERVICES
- ADOLESCENTS 35KG WOULD BE DOSED AS ADULTS





# SUMMARY

- PHARMACISTS HAVE THE SKILLS AND OPPORTUNITY TO PROVIDE TIMELY ACCESS TO HIV POST-EXPOSURE PROPHYLAXIS FOR PATIENTS WITH HIGH AND MODERATE EXPOSURES TO HIV W/IN 72HRS.
- PHARMACISTS CAN LINK PATIENTS TO PROVIDERS WHO CAN DO THE BASELINE AND FOLLOW-UP TESTING FOR HIV, AND OTHER SEXUALLY TRANSMITTED DISEASES AND BLOODBORNE PATHOGENS.
- PHARMACISTS CAN CHOOSE AN APPROPRIATE PEP REGIMEN AND DISPENSE TO PATIENTS FOR STARTING ASAP FOLLOWING EXPOSURE.
- PHARMACISTS HAVE THE SKILLS TO COUNSEL PATIENTS ABOUT ADHERENCE, SIDE-EFFECTS, IMPORTANCE IN LINKING TO CARE AND CONSIDER TRANSITION PEP TO PrEP FOR PATIENTS WHO WOULD BENEFIT.





# LEGAL REQUIREMENTS OF FURNISHING IN CALIFORNIA



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# LEARNING OBJECTIVE

- DEFINE KEY ASPECTS OF LEGISLATION AUTHORIZING PHARMACISTS TO FURNISH PREP AND PEP IN CALIFORNIA





# PREP

PRIOR TO FURNISHING, A PHARMACIST MUST COMPLETE A TRAINING PROGRAM  
APPROVED BY THE BOARD





# PREP

FURNISHING RESTRICTIONS: AT LEAST A 30-DAY SUPPLY TO 60-DAY SUPPLY UNDER SPECIFIED CONDITIONS

- DOCUMENTED NEGATIVE HIV TEST
- NO REPORTED SIGNS OR SYMPTOMS OF ACUTE HIV INFECTION
- NO REPORTED CONTRAINDICATED MEDICATIONS
- MANDATORY COUNSELING





# PEP

## FURNISHING RESTRICTIONS:

- PATIENT SCREENING TO DETERMINE IF EXPOSURE OCCURRED WITHIN THE PREVIOUS 72 HOURS
- PATIENT MEETS CLINICAL CRITERIA IN CDC GUIDELINES
- HIV TESTING IS PROVIDED UNDER CLIA PROVISION
- MANDATORY COUNSELING
- NOTIFICATION TO PRIMARY CARE PROVIDER





# PREP AND PEP

- CDC GUIDELINES PREP – 2017 PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2017 UPDATE: A CLINICAL PRACTICE GUIDELINE
- CDC GUIDELINES PEP – UPDATED GUIDELINES FOR ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE TO HIV-UNITED STATES, 2016





# HIV TESTING



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# LEARNING OBJECTIVES

- DETERMINE RECOMMENDED HIV TEST BASED ON CLINICAL CIRCUMSTANCES
- IDENTIFY PATHWAY FOR TESTING OUTSIDE TRADITIONS SETTINGS





# HIV TESTING REQUIREMENTS IN SB159

- HIV TESTING IS ONE IMPORTANT PART OF THE RECOMMENDED LABORATORY TESTING THAT PATIENTS SHOULD RECEIVE AS RECOMMENDED IN CDC GUIDELINES (LINKS PROVIDED)
- TIMELY TESTING AND TREATMENT, AS APPLICABLE, IS ALSO RECOMMENDED FOR RENAL FUNCTION, HEPATITIS B, HEPATITIS C, SEXUALLY TRANSMITTED DISEASES, AND PREGNANCY
- THIS TESTING COULD OCCUR AT OR BE ARRANGED BY THE PHARMACY OR THE CLINICAL LOCATION WHERE LONG-TERM FOLLOW-UP WILL OCCUR
- PHARMACIES ARE ENCOURAGED TO ESTABLISH PROTOCOLS FOR WHERE THIS TESTING WILL OCCUR





# HIV TESTING IN PREP AND PEP

Testing Situation	Timing of Test	Location of Testing	Follow-up testing
<b>PrEP</b>	negative HIV test result within the previous 7 days	Patient can bring documentation of a test or be tested at the pharmacy	Patients on PrEP are recommended to receive HIV testing every 3 months
<b>PEP</b>	PEP is an emergency and can be started before HIV testing	HIV testing can occur at the pharmacy or at a referral site	Patient on PEP are recommended to receive HIV testing in 6 and 12 weeks



# OPTIMAL HIV TESTS FOR DIFFERENT SITUATIONS

Testing Situation	Recommended Test	Comments
<b>HIV exposure in last month or symptoms of acute HIV</b>	HIV RNA PCR and HIV antigen/antibody test	If HIV infected – consider rapid HIV treatment
<b>Normal</b>	HIV antigen/antibody test (4 <sup>th</sup> generation) - preferred  HIV antibody only testing is an alternative	Lab-based is more sensitive than rapid CLIA waived tests
<b>“Stay-at-Home” Order; in-person visits limited</b>	FDA-approved in-home HIV antibody test on oral fluid*	Less sensitive but an option during the pandemic

\* CDC Dear Colleague Letter: <https://www.cdc.gov/hiv/policies/dear-colleague/dcl/051520.html>



# HIV TESTING IN NON-CLINICAL SETTINGS

- MULTIPLE CLIA WAIVED HIV TESTS ARE COMMERCIALY AVAILABLE FOR RAPID TESTING WHICH COULD FACILITATE THE PROVISION OF PREP AND PEP IN PHARMACY SETTINGS
- PHARMACISTS ARE ONE OF THE CATEGORIES OF PEOPLE AUTHORIZED TO PERFORM CLIA WAIVED TESTS IN ACCORDANCE WITH THE FEDERAL CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (42 U.S.C. SEC. 263A) AND AS SPECIFIED IN CALIFORNIA BUSINESS AND PROFESSIONS CODE (BPC 1206.5)
- OTHER PHARMACY PERSONNEL CAN PERFORM CLIA WAIVED HIV TESTING IF THEY HAVE RECEIVED TEST COUNSELOR TRAINING AND MEET REQUIREMENTS AS SPECIFIED BY CALIFORNIA HEALTH AND SAFETY CODE (HSC) 120917





# PATIENT FINANCIAL CONSIDERATIONS



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# LEARNING OBJECTIVES

- DISTINGUISH REIMBURSEMENT RESOURCES FOR INSURED AND UNINSURED INDIVIDUALS





# PATIENT FINANCIAL CONSIDERATIONS

- TWO CATEGORIES OF PrEP AND PEP COSTS SHOULD BE CONSIDERED FOR ALL PATIENTS:
  - PrEP AND PEP MEDICATION COST INCLUDING COPAYS
  - OUT-OF-POCKET COSTS FOR CLINIC VISIT FEES, LABORATORY TESTING, AND MEDICATIONS TO TREAT COMMON SEXUALLY TRANSMITTED INFECTIONS
- THESE COSTS ARE GENERALLY COVERED BUT OFTEN REQUIRE COMBINING INSURANCE AND ASSISTANCE PLANS





# PROGRAMS TO COVER COSTS OF PREP AND PEP

Program	PrEP/PEP medication coverage	Clinic and lab testing
Comprehensive insurance plans (including Medi-Cal)	Yes, PrEP copays to be removed by end of 2020	Covered, may have copay
Manufacturer patient assistance	Yes (full coverage)	No
Federal Ready, Set, PrEP program	PrEP only (full coverage)	No
California PrEP Assistance Program	Covered in select situations when not covered by other programs	Yes (full coverage)





# THIRD PARTY REIMBURSEMENT

- COMPREHENSIVE INSURANCE PLANS INCLUDING MEDI-CAL AND MEDICARE COVER PREP AND PEP
  - SB 159 ELIMINATED PRIOR AUTHORIZATIONS FOR PREP AND PEP
- UNITED STATES PREVENTIVE SERVICES TASK FORCE (USPSTF) ISSUED A GRADE “A” RECOMMENDATION FOR PREP FOR PERSONS WHO ARE AT HIGH RISK OF HIV ACQUISITION (JUNE 2019)
- THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) STATES A MEDICAL INSURER MUST COVER, AND MAY NOT IMPOSE ANY COST SHARING REQUIREMENT FOR, ANY EVIDENCE-BASED PREVENTIVE ITEMS OR SERVICES THAT HAVE A GRADE OF “A” OR “B”
- PREP COPAYS ARE BEING REMOVED FROM PLANS STARTING IN 2021





# MANUFACTURER ADVANCING ACCESS PROGRAM

- UNINSURED CLIENTS ENROLL IN THE PATIENT ASSISTANCE PROGRAM (PAP) AND RECEIVE EITHER TRUVADA OR DESCovy FREE OF CHARGE.
- INSURED CLIENTS ENROLL IN THE CO-PAYMENT ASSISTANCE PROGRAM AND RECEIVE A CO-PAY COUPON CARD FROM MANUFACTURER THAT COVER CO-PAYMENTS TO AN ANNUAL MAXIMUM THRESHOLD OF \$7,200





# MANUFACTURER ADVANCING ACCESS PROGRAM

## REQUESTED PATIENT SUPPORT OFFERINGS

Please select patient support offerings  
CHECK ALL BOXES THAT APPLY



☐ **Benefits Investigation**

Help research and verify specific insurance coverage for Gilead medication



☐ **Prior Authorization and Appeals Information**

Provides information to your doctor if your insurance company requires your doctor to complete a Prior Authorization for your Gilead medication. Provides follow up with health insurers regarding the status of your Prior Authorization request and sends updates on information needed.



☐ **Patient Assistance Program (PAP) or Medication Assistance Program (MAP) Eligibility Screening**

If you lack insurance coverage and meet the program criteria, you may be eligible to receive Gilead medication free of charge



☐ **Co-Pay Coupon Program Enrollment**

If you are eligible, Gilead's Co-Pay Coupon may help lower your out-of-pocket costs. Patients enrolled in government prescription drug programs, such as Medicare Part D and Medicaid are not eligible for the co-pay coupon.

## GILEAD MEDICATION PRESCRIBED

Product Name\*

Select One ▼

## PATIENT INFORMATION

\* Indicates required field.

\*Patient First Name:

\*Patient Last Name:

\*Address:

\*City:

\*State:  ▼

Email:

\*Preferred Language:

\*Phone #:

SSN (last 4 digits):

\*DOB:

Alternate Contact Name:

Alternate Contact Phone #:

Relationship:

## CONTACT AUTHORIZATION

\*I authorize Advancing Access to leave a detailed message, including the name of my prescription, if I am unavailable when they call. ☐ Yes ☐ No

I authorize Advancing Access to send me correspondence via U.S. mail. This includes, but is not limited to approval/denial letters for the Patient Assistance Program, reminder letters for re-enrollment periods, etc. If I select "No", I understand that all communication will be via phone. ☐ Yes ☐ No

Continue





**The Ready, Set, PrEP program  
makes PrEP medications available  
at no cost for people who qualify.**

## **HOW CAN I ENROLL IN THE READY, SET, PrEP PROGRAM?**

To receive PrEP medication  
through the Ready, Set, PrEP  
program, you must:

- ✓ Test negative for HIV
- ✓ Have a valid prescription  
from your healthcare  
provider
- ✓ *Not* have insurance that  
covers prescription drugs

## **WHERE CAN I LEARN MORE AND APPLY FOR THE PROGRAM?**

Find out if PrEP medication is right for you.  
Talk to your healthcare professional or  
find a provider at [locator.hiv.gov](https://locator.hiv.gov).

→ **GETYOURPREP.COM**

→ **855.447.8410**







# PrEP-AP

The State of California's **assistance program** for the prevention of HIV helps cover medical costs related to getting pre-exposure prophylaxis



## Welcome to California Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)

The California Pre-Exposure Prophylaxis Assistance Program (PrEP-AP) was established in 2018 to facilitate access to medications for the prevention of HIV for HIV-negative individuals. There are over 5,000 pharmacies statewide where clients can access these drugs.





# HOW TO BECOME A PREP-AP PROVIDER

- PHARMACY/PHARMACIST CONTACTS CDPH/OA ([HTTPS://WWW.CDPH.CA.GOV/PROGRAMS/CID/DOA/PAGES/OAADAP.ASPX#PREP](https://www.cdph.ca.gov/Programs/CID/DOA/PAGES/OAADAP.ASPX#PREP))
- PHARMACY CONTRACTS WITH CDPH/OA AS AN ENROLLMENT SITE FOR A DEFINED LIMITED ENROLLMENT SERVICE, TO ENROLL INTO PREP-AP TEMPORARY COVERAGE.
- PHARMACIST COMPLETES THE PREP-AP TRAINING TO ENROLL NEW CLIENTS IN PREP-AP TEMPORARY COVERAGE.





# PREP-AP COVERAGE SUMMARY

- PHARMACIST WILL RECEIVE PAYMENT FOR EACH CLIENT THEY ENROLL IN PREP-AP TEMPORARY COVERAGE.
- PREP-AP TEMPORARY COVERAGE PROVIDES CLIENTS WITH 30 DAYS OF TEMPORARY ELIGIBILITY IN ORDER TO OBTAIN PREP OR PEP ) .
- PREP-AP TEMPORARY COVERAGE WILL ONLY PAY FOR
  - PREP MEDICATION: 30-DAY SUPPLY (CLIENT CAN ENROLL IN PREP-AP TEMPORARY COVERAGE UP TO TWO TIMES TO OBTAIN TWO 30-DAY DISPENSES EVERY TWO YEARS TO RECEIVE THE 60-DAY SUPPLY PER SB 159. PLEASE NOTE: THE DISPENSES CAN BE CONSECUTIVE, I.E. ONE DISPENSE ON MARCH 1 AND RETURN FOR SECOND DISPENSE ON APRIL 1), OR
  - PEP MEDICATION: 30-DAY SUPPLY.





# CASES



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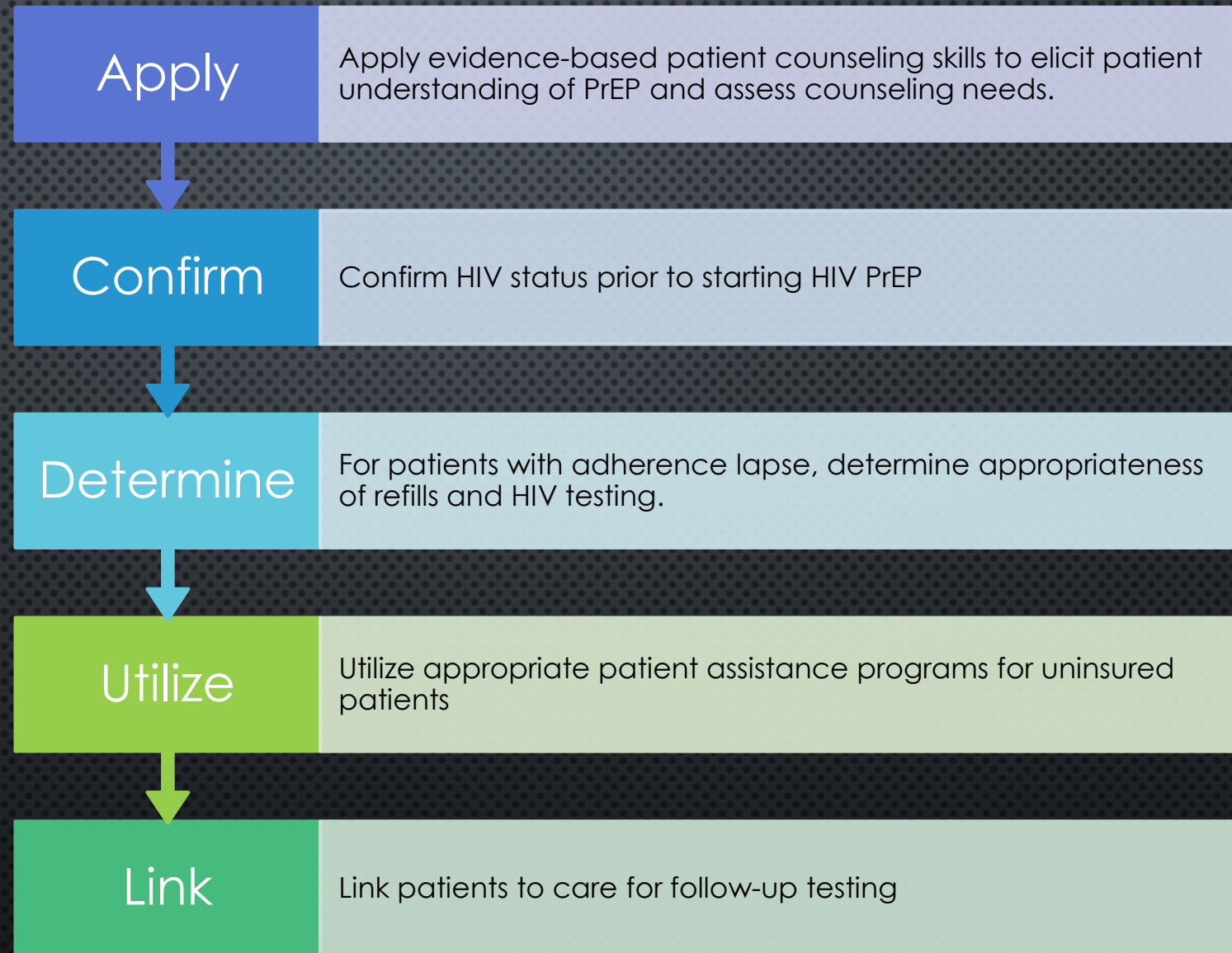
# PREP CASE

20 YO CIS-MALE IS PRESENTING TO PHARMACY REQUESTING REFILL OF PREP AND ASSISTANCE WITH PAP PROGRAM. PATIENT PICKED UP 30 DAY SUPPLY OF TENOFOVIR DF/EMTRICITABINE (TRUVADA) 3 MONTH AGO AND HAS 2 REFILLS REMAINING ON FILE. PATIENT WENT TO MOBILE HIV TESTING IN AREA 2 DAYS AGO AND HAS HIV ANTIBODY/ANTIGEN NEGATIVE TEST RESULTS WITH HIM.





# LEARNING OBJECTIVES





# ROLE OF COMMUNITY PHARMACISTS IN PREP

- ALL STAFF IN THE PHARMACY NEED TO REASSURE PATIENT THAT PHARMACY HAS THE TOOLS AND SKILLS TO ASSIST THIS PATIENT
  - CLERK, TECHNICIANS, INTERNS, PHARMACISTS WORK AS A TEAM TO SUPPORT THE HEALTH OF PATIENTS.
- ELICIT FROM PATIENT HIS CURRENT UNDERSTANDING OF HOW PREP WILL BENEFIT HIM AND ADHERENCE TO PREP REGIMEN.

TAKE ONE MINUTE TO WRITE DOWN THE OPEN-ENDED QUESTION YOU WOULD ASK TO ELICIT THIS INFORMATION WITH PATIENT.





# COUNSELING WITH PATIENT

"IT IS SO GREAT TO SEE YOU BACK HERE! THANK YOU FOR COMING IN TODAY. BEFORE WE WORK ON YOUR REFILL, WOULD IT BE OKAY IF WE TALKED ABOUT HOW HIV PREP IS WORKING FOR YOU?"

YES, NO PROBLEM I HAVE ABOUT 15 MINUTES TO CHAT.

"TELL ME ABOUT YOUR CHOICE TO START HIV PREP AND WHAT, IF ANY, PROBLEMS OR CHALLENGES YOU HAD TAKING YOUR MEDICINE EVERY DAY."

I CHOSE TO START PREP AFTER DISCUSSING WITH MY PROVIDER SINCE I HAVE LOTS OF SEX AND DO NOT ALWAYS USE CONDOMS. I SAW THE ADS FOR PREP WHEN USING TINDER FOR HOOKUPS. I WAS SO HAPPY TO GET THE PRESCRIPTION AND TOOK IT EVERYDAY FOR THE FIRST MONTH, EACH MORNING WHEN I WOKE UP. I USED A PHONE APP TO HELP REMIND ME. ABOUT 3 WEEKS INTO THIS PRESCRIPTION, I LOST MY JOB AND SO KNEW I WOULD ALSO LOSE MY INSURANCE, SO I DID NOT GO BACK TO SEE MY PROVIDER OR GET A REFILL SINCE I COULD NOT AFFORD THE MEDICATION. ONE OF MY FRIENDS TOLD ME HE GOT ENROLLED IN A PROGRAM AT THIS PHARMACY THAT HELPS HIM AFFORD HIS PREP, SO I THOUGHT I WOULD GET IN THAT PROGRAM TOO.

TAKE A MINUTE TO WRITE DOWN YOUR RESPONSE TO THIS PATIENT – USE REFLECTIVE LISTENING





# COUNSELING WITH PATIENT

“YOU KNOW A LOT ABOUT PrEP AND WERE ABLE TO MAKE IT A REGULAR PART OF YOUR DAILY ROUTINE, WITH SOME REMINDERS FROM A PHONE APP. HEALTHY SEX IS IMPORTANT TO YOU, AND THAT DOES NOT ALWAYS INCLUDE CONDOMS, SO YOU WOULD LIKE TO CONTINUE TO USE MEDICINE TO PREVENT HIV INFECTION. LET ME KNOW IF I HAVE THAT RIGHT AND WHAT YOU KNOW ABOUT TESTING FOR HIV AND SEXUALLY TRANSMITTED DISEASES WHILE TAKING PrEP?”

YEP — YOU HAVE THAT RIGHT. I KNOW I NEED TO BE HIV NEGATIVE TO TAKE PrEP, SO HERE ARE MY TEST RESULTS FROM TWO DAYS AGO. ARE THERE OTHER TESTS I NEED BEFORE YOU WILL GIVE ME THIS MEDICINE?





# PHARMACY NEEDS PRIOR TO DISPENSING PREP

- CONFIRM HIV NEGATIVE STATUS — WITHIN 7 DAYS FROM DISPENSING
- ASSESS FOR SYMPTOMS OF ACUTE HIV INFECTION
- LINK PATIENT TO CARE FOR PROVIDER TO DO FOLLOW-UP RENAL FUNCTION AND STI TESTING.
- CONFIRM PATIENT COMMITTED TO TAKING MEDICINE DAILY.
- HAS ACCESS TO OTHER PREVENTION TOOLS AS NEEDED (I.E. CONDOMS, STERILE SYRINGES, BIRTH CONTROL)

IS THIS PATIENT APPROPRIATE FOR REFILL OF TENOFOVIR DF/EMTRICITABINE?





# CASE

“I DO NOT NEED ANY ADDITIONAL TESTS BEFORE GETTING YOU YOUR PrEP MEDICATION. I DO HAVE A FEW MORE QUESTIONS, IS THAT OKAY?”

SURE

“TELL ME IF YOU HAVE NOTICED ANY CHANGES TO YOUR HEALTH IN THE PAST MONTH – ANY FLU-LIKE SYMPTOMS?”

NO CHANGES TO MY HEALTH, I FEEL GREAT.

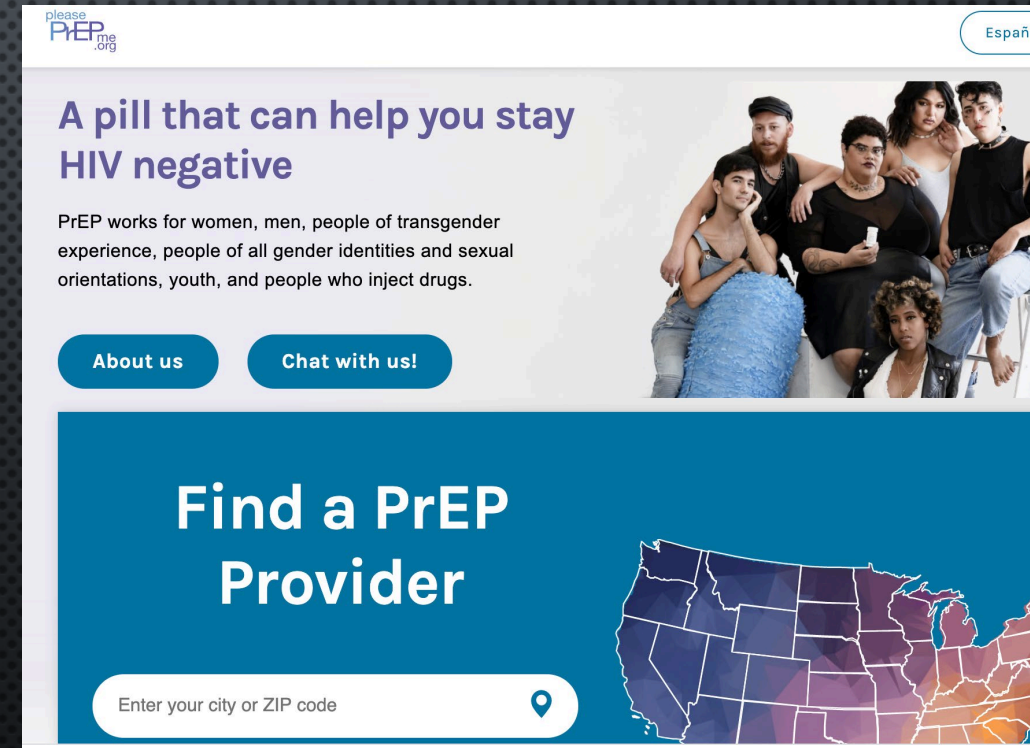
“HIV PrEP IS VERY EFFECTIVE IN PREVENTING HIV WHEN YOU SWALLOW IT EVERY DAY, HOWEVER PrEP WILL NOT PREVENT OTHER SEXUALLY TRANSMITTED INFECTIONS LIKE SYPHILIS OR CHLAMYDIA. WE DO NEED TO GET YOU BACK IN TOUCH WITH YOUR PROVIDER SO THEY CAN TEST YOU FOR THESE STIs. WHAT IDEAS DO YOU HAVE ABOUT CONNECTING WITH YOUR PROVIDER?”





# LINKAGE TO CARE

- PATIENTS AND PHARMACIES CAN ACCESS PROVIDERS OF PrEP SERVICES VIA LOCAL PUBLIC HEALTH DEPARTMENTS OR PLEASEPREPME.ORG



The screenshot shows the homepage of pleasePREPME.org. At the top left is the logo 'please PREP me .org'. At the top right is a language toggle button labeled 'Español'. The main heading is 'A pill that can help you stay HIV negative'. Below this is a paragraph: 'PrEP works for women, men, people of transgender experience, people of all gender identities and sexual orientations, youth, and people who inject drugs.' To the right of the text is a group photo of diverse young people. Below the text are two buttons: 'About us' and 'Chat with us!'. The bottom section has a blue background with the text 'Find a PrEP Provider' and a search bar with the placeholder 'Enter your city or ZIP code' and a location pin icon. To the right of the search bar is a map of the United States with states colored in shades of purple and blue.

please  
PREP  
me  
.org

Español

## A pill that can help you stay HIV negative

PrEP works for women, men, people of transgender experience, people of all gender identities and sexual orientations, youth, and people who inject drugs.

About us Chat with us!

## Find a PrEP Provider

Enter your city or ZIP code





## WELCOME TO

# Ending the HIV Epidemic: Ready, Set, PrEP



Pre-exposure prophylaxis (or PrEP) medications are prescription medications that people take daily to significantly reduce their risk of acquiring HIV through sex. PrEP can stop HIV from taking hold and spreading throughout the body. Two medications are FDA-approved for use as PrEP: TRUVADA and DESCOVY. When taken daily, PrEP is highly effective for preventing HIV from sex.

The *Ready, Set, PrEP* program makes PrEP medication available at no cost for qualifying recipients. To receive PrEP medication through this program, you must:

- Lack prescription drug coverage
- Be tested for HIV with a negative result
- Have a prescription for PrEP

Talk to your healthcare provider or find a provider at [HIV.gov Locator](https://www.hiv.gov/locator) to find out if PrEP is right for you.

## PATIENT ASSISTANCE PROGRAM

GETYOURPREP.ORG

ABLE TO ENROLL PATIENTS  
AS HEALTHCARE PROVIDER





# MANUFACTURE'S ADVANCING ACCESS PROGRAM

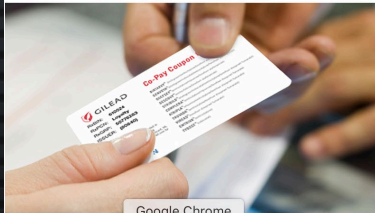
gileadadvancingaccess.com

## Gilead's Advancing Access® Program Is Here to Help You

**Gilead's Advancing Access** program is committed to helping you afford your medication no matter your situation. Whether you have insurance or not, we can explore potential coverage options that might be right for you.


Our dedicated program specialists are here to help you. Talk to someone right away by calling **1-800-226-2056**.  
Advancing Access phone lines are open M - F 9am - 8pm ET. If you reach us after hours, leave a message, and we will call you back during the next business day.

### The Advancing Access CO-PAY COUPON PROGRAM



Google Chrome

### The Advancing Access PATIENT SUPPORT PROGRAM



Enroll today and get access to the live support you need for your Gilead medication.





# CASE

"THANK YOU FOR SHARING YOUR EXPERIENCE WITH PREP AND HOW IT HELPS YOU. I AM ABLE TO SUPPORT YOUR RESTART OF PREP TODAY, THANK YOU FOR BRINGING IN YOUR HIV TEST RESULT SO I CAN DO THAT. LET'S GET YOU SIGNED UP WITH A PATIENT ASSISTANCE PROGRAM. DO I HAVE YOUR CONSENT TO DO THIS WITH YOU?"

YES – THANK YOU.

"NOW THAT WE HAVE YOU SIGNED UP, HERE IS A 30 DAY SUPPLY OF TRUVADA WHICH I REFILLED FROM YOUR PREVIOUS PRESCRIPTION. I HAVE SENT A FAX TO YOUR PROVIDER THAT YOU WERE HERE TODAY AND NEED TO GET A F/U APPOINTMENT WITH THE CLINIC, AND THAT YOUR INSURANCE HAS LAPSED. I LET THEM KNOW YOU HAD A RECENT HIV NEGATIVE TEST. HERE IS THE PHONE NUMBER FOR YOUR PROVIDER TO CALL AND SCHEDULE AN APPOINTMENT. I WILL LOOK FOR A NEW PRESCRIPTION FROM YOUR PROVIDER FOR YOUR NEXT TRUVADA REFILL. WHAT OTHER QUESTIONS OR CONCERNS DO YOU HAVE FOR ME TODAY?"





# SUMMARY

- PATIENTS WITH ADHERENCE LAPSE IN PrEP WILL NEED TO CONFIRM HIV NEGATIVE STATUS BEFORE REFILLS.
- PHARMACIES ARE IDEAL SPACES FOR PATIENTS TO ACCESS SERVICES AND RECEIVE ADHERENCE COUNSELING AND SUPPORT WITH PrEP.
- PHARMACIES CAN ENROLL PATIENTS IN PATIENT ASSISTANCE PROGRAMS AND COPAY SUPPORT PROGRAMS.
- LINKAGE TO PROVIDERS FOR ONGOING LABORATORY MONITORING FOR RENAL FUNCTION AND STIs IS CRITICAL FOR PHARMACISTS TO ACHIEVE QUALITY PATIENT CARE.
- UTILIZING MOTIVATIONAL INTERVIEWING AND STRENGTH-BASED COUNSELING WITH OPEN-ENDED QUESTIONS ENGAGES PATIENTS EFFECTIVELY FOR THESE SENSITIVE CONVERSATIONS.





# PHARMACISTS AND PEP



CALIFORNIA STATE BOARD OF PHARMACY  
Be aware and take care. Talk to your Pharmacist!

[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)



# LEARNING OBJECTIVES

- ASSESS THE RISK OF EXPOSURE FOR HIV INFECTION
- USE NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS GUIDELINES TO DETERMINE APPROPRIATENESS OF MEDICATIONS.
- COUNSEL PATIENTS REGARDING APPROPRIATENESS OF NPEP.
- CHOOSE AND DISPENSE A APPROPRIATE NPEP REGIMEN.
- ACCESS PATIENT-ASSISTANCE PROGRAMS AS NEEDED FOR PATIENTS.
- LINK PATIENTS TO PRIMARY CARE FOR FOLLOW-UP TESTING AND MONITORING.





# CASE DESCRIPTION

55 YO TRANSWOMAN COMES INTO PHARMACY WITH CONCERN ABOUT CONDOM-LESS RECEPTIVE ANAL INTERCOURSE APPROXIMATELY 24 HOURS AGO. THIS WOMAN KNOWS HER PARTNER, BUT DOES NOT KNOW HIS HIV STATUS. SHE IS WONDERING IF THERE IS A MEDICINE SHE CAN START NOW TO REDUCE HER RISK OF HIV INFECTION.





# RISK ASSESSMENT

IN THIS CASE, IDENTIFY THE COMPONENTS OF AN APPROPRIATE RISK ASSESSMENT:

- 1) WHAT INFECTIOUS BODY FLUID MIGHT SHE HAVE BEEN EXPOSED TO?
- 2) WAS EXPOSURE TO INFECTIOUS BODY FLUID IN MUCOSA THAT COULD CAUSE INFECTION?
- 3) HOW LIKELY IS IT THAT THAT BODY FLUID MAY HAVE CONTAINED INFECTIOUS HIV?
- 4) IS SHE PRESENTING FOR CARE IN A TIME PERIOD WHEN POST-EXPOSURE PROPHYLAXIS WOULD BE APPROPRIATE?





# INFECTIOUS BODY FLUIDS

- SEMEN
- VAGINAL FLUIDS
- VISIBLE BLOOD

NOT INFECTIOUS BODY FLUIDS, MEANING EXPOSURE TO THESE BODY FLUIDS CARRIES NO RISK OF HIV TRANSMISSION WHEN SOURCE IS KNOWN TO BE LIVING WITH HIV:

SALIVA

SWEAT

TEARS





# LIKELIHOOD OF BODY FLUID CONTAINING HIV INFECTION

- HIGHEST WHEN SOURCE OF BODY FLUID KNOWN TO BE LIVING WITH HIV INFECTION AND NOT TAKING MEDICATIONS
  - PEOPLE LIVING WITH HIV INFECTION AND ON MEDICINES ACHIEVING UNDETECTABLE VL DO NOT TRANSMIT HIV TO PARTNERS. UNDETECTABLE = UNTRANSMITTABLE
- WHEN HIV STATUS OF SOURCE IS UNKNOWN, CAN CONTINUE BY COUNSELING “IF PERSON WAS LIVING WITH HIV”.
- PEOPLE WHO ARE KNOWN TO BE NEGATIVE FOR HIV INFECTION, CARRY NO RISK OF TRANSMISSION, REGARDLESS OF BODY FLUID EXPOSURE.





# EXPOSURE OF INFECTIOUS BODY FLUIDS TO AREAS THAT CAN CAUSE TRANSMISSION

- RECTAL MUCOSA
- VAGINAL MUCOSA
- INJECTION INTO SKIN — IE BLOOD SHARING FROM USED NEEDLES

EXPOSURE TO INFECTIOUS BODY FLUIDS ON IN-TACT SKIN CARRIES NO RISK OF HIV TRANSMISSION.





# TIMING OF HIV POST-EXPOSURE PROPHYLAXIS

- REASONABLE TO START HIV PEP WITHIN 72 HOURS OF INFECTIOUS BODY FLUID FROM A SOURCE PERSON CONSIDERED TO BE LIVING WITH HIV AND DETECTABLE VIRAL LOAD.
- STUDIES IN ANIMAL MODELS SUGGEST THAT STARTING ASAP AFTER EXPOSURE IMPROVES EFFICACY OF PEP.
  - THESE SAME STUDIES SUGGESTED THAT STARTING PEP BEYOND 72 HOURS DID NOT CONFER EFFICACY.
- IMPORTANT TO RESPOND PROMPTLY AS STARTING HOUR 12 WILL HAVE IMPROVED EFFICACY THAN STARTING AT HOUR 36 FROM EXPOSURE.
  - INAPPROPRIATE TO TELL PATIENTS TO “COME BACK TOMORROW” AND START MEDICATIONS.





# RISK ASSESSMENT

IN THIS CASE, IDENTIFY THE COMPONENTS OF AN APPROPRIATE RISK ASSESSMENT:

1) WHAT INFECTIOUS BODY FLUID MIGHT SHE HAVE BEEN EXPOSED TO?

YES - SEMEN

2) WAS INFECTIOUS BODY FLUID TO PART OF BODY THAT COULD CAUSE TRANSMISSION?

YES – RECTAL MUCOSA

3) HOW LIKELY IS IT THAT THAT BODY FLUID MAY HAVE CONTAINED INFECTIOUS HIV?

POSSIBLE – SOURCE HIV STATUS UNKNOWN

4) IS SHE PRESENTING FOR CARE IN A TIME PERIOD WHEN POST-EXPOSURE PROPHYLAXIS WOULD BE APPROPRIATE?

YES – HOUR 24





# CHOOSING PEP REGIMEN

CDC NPEP GUIDELINES SUGGEST THAT PEP REGIMENS SHOULD BE A 28 DAY COURSE OF EFFECTIVE COMBINATION HIV TREATMENT REGIMENS.

CURRENT DHHS GUIDELINES ON RECOMMENDED HIV TREATMENT REGIMENS INCLUDE:

BICTEGRAVIR-TENOFOVIR ALAFENAMIDE – EMTRICITABINE (BIKTARVY) ONE DAILY

DOLUTEGRAVIR 50MG DAILY (TIVICAY) + EITHER TENOFOVIR ALAFENAMIDE/EMTRICITABINE (DESCOVY) OR TENOFOVIR DIPROXIL FUMERATE/EMTRICITABINE (TRUVADA) ONE DAILY





# PEP REGIMEN

- MOST IMPORTANT TO CHOOSE A REGIMEN THAT PATIENT CAN START ASAP AND IS AN EFFECTIVE DHHS-RECOMMENDED HIV TREATMENT REGIMEN. OTHER OPTIONS MAY BE REASONABLE, BUT CAN HAVE MORE DRUG-DRUG INTERACTIONS TO BE REVIEWED:
- ELVITEGRAVIR-CONTAINING SINGLE TABLET REGIMENS (I.E. GENVOYA OR STRIBILD)
- PROTEASE INHIBITOR CONTAINING REGIMENS: (I.E. DARUNAVIR 800MG DAILY + BOOSTER (EITHER RITONAVIR 100MG DAILY OR COBICISTAT) + TENOFOVIR/EMTRICITABINE (AS EITHER DESCOVY OR TRUVADA).





# CASE – CHOOSING A REGIMEN

THIS PATIENT HAS MEDICAL AND ALSO TAKES ESTROGENS, SPIRONOLACTONE, METFORMIN 1000MG BID FLUTICASONE-SALMETEROL INHALER AND PRN ALBUTEROL.

YOU HAVE BICTEGRAVIR-TENOFOVIR ALAFENAMIDE-EMTRICTABINE (BIKTARVY) ON SHELF, SO CAN DISPENSE THIS MEDICATION AS IT IS AN EFFECTIVE HIV TREATMENT REGIMEN RECOMMENDED BY CURRENT DHHS GUIDELINES. IT IS ALSO ON THE MEDICAL FORMULARY.

IN ADDITION, IT HAS FEWER DRUG-DRUG INTERACTIONS THAN THE ELVITEGRAVIR/COBICISTAT SINGLE TABLET REGIMENS OR PROTEASE-INHIBITOR REGIMENS AND DOLUTEGRAVIR.

FLUTICASONE LEVELS CAN BE INCREASED WITH RITONAVIR AND COBICISTAT

METFORMIN LEVELS CAN BE INCREASED WITH DOLUTEGRAVIR AND RECOMMENDED MAXIMUM DOSE IS METFORMIN 1000MG/DAY FOR PATIENTS TAKING DOLUTEGRAVIR.





# ACCESSING MEDICATIONS VIA PATIENT ASSISTANCE PROGRAMS

- PATIENT ASSISTANCE PROGRAMS ARE AVAILABLE FOR DISPENSING 30 DAY SUPPLY OF PEP REGIMENS.
- WOULD ONLY NEED TO ACCESS ONE PROGRAM IF ABLE TO START PATIENT ON SINGLE-TABLET REGIMENS. FOR MULTIPLE TABLET REGIMENS, MAY NEED TO CONTACT MULTIPLE PAP.





# COUNSELING PATIENTS

- REASSURE THAT STARTING AND COMPLETING 28 DAY TREATMENT COURSE CAN REDUCE RISK OF HIV TRANSMISSION BY 80%
  - DOES NOT ELIMINATE RISK OF HIV TRANSMISSION
- IF DO NOT COMPLETE FULL 28 DAY COURSE, PATIENT DOES NOT GET BENEFIT OF MEDICATIONS TO REDUCE RISK OF HIV TRANSMISSION
- GIVEN 28 DAY TREATMENT COURSE, PATIENT IS NOT AT RISK FOR LONG-TERM COMPLICATIONS FROM MEDICATIONS
- SOME PEOPLE EXPERIENCE SHORT TERM SIDE-EFFECTS — LIKE NAUSEA, DIARRHEA, HEADACHES, INSOMNIA
  - CAN TAKE MOST MEDICINES WITH FOOD, WHICH WILL LESSEN GI EFFECTS
  - COULD ALSO USE ANTIEMETICS (I.E. GINGER) TO MITIGATE NAUSEA EFFECTS
  - THESE EFFECTS LIKELY TO LESSEN OVER DAYS/WEEKS AND CERTAINLY ONCE COMPLETE REGIMEN AND STOP MEDICINES.





# LINKAGE TO CARE

- ESSENTIAL TO ENSURE PATIENT HAS APPOINTMENT WITH PROVIDER WHO CAN DO BASELINE HIV, HEPATITIS, STI TESTING, ALONG WITH PLAN FOR F/U HIV TESTING.
- PATIENTS SHOULD BE SEEN URGENTLY WITHIN FIRST FEW DAYS OF STARTING HIV PEP REGIMEN.
  - PHARMACIES PROVIDING PEP CAN PREPARE FOR SUCCESSFUL LINKAGE BY CONTACTING APPROPRIATE PROVIDERS IN THEIR COMMUNITY AND DEVELOP A LINKAGE TO CARE PROTOCOL WITH THOSE PROVIDERS AND CLINICS.





# SUMMARY

- ASSESS RISK OF EXPOSURE.
- ENSURE START OF PEP CAN BE < 72 HOUR FROM TIME SINCE EXPOSURE.
- COUNSEL PATIENT ABOUT RISK AND APPROPRIATENESS OF PEP.
- FOR PATIENTS APPROPRIATE FOR PEP, START HIV TREATMENT REGIMEN ASAP FOR 28 DAY TREATMENT COURSE.
  - ACCESS PATIENT ASSISTANCE PROGRAMS AS NEEDED FOR UNINSURED PATIENTS OR THOSE NEEDING COPAY ASSISTANCE
- COUNSEL PATIENT ON POSSIBLE SHORT-TERM SIDE EFFECTS AND MITIGATION STRATEGIES
- LINK PATIENT TO CARE FOR LABORATORY MONITORING (BASELINE AND F/U HIV TESTING)





# Financial Resources

- PrEP-AP Webpage:

<https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAadap.aspx#prep>





# LINKAGE TO CARE RESOURCES

- PLEASE PREP ME

<https://www.pleaseprepme.org/>

- AAHIM

- LOCAL COUNTY HEALTH DEPARTMENT

[HTTPS://WWW.CDPH.CA.GOV/PAGES/LOCALHEALTHSERVICESANDOFFICES.ASPX#](https://www.cdph.ca.gov/PAGES/LOCALHEALTHSERVICESANDOFFICES.ASPX#)





# CLINICAL RESOURCES

- CDC GUIDELINES
  - [HTTPS://WWW.CDC.GOV/HIV/CLINICIANS/PREVENTION/PREP-AND-PEP.HTML](https://www.cdc.gov/hiv/clinicians/prevention/prep-and-pep.html)
- NON-OCCUPATIONAL PEP GUIDELINE
  - [HTTPS://STACKS.CDC.GOV/VIEW/CDC/38856](https://stacks.cdc.gov/view/cdc/38856)
- NIH GUIDELINES
  - [HTTPS://AIDSINFO.NIH.GOV/GUIDELINES](https://aidsinfo.nih.gov/guidelines)
- PACIFIC AIDS EDUCATION AND TRAINING CENTER
  - [HTTP://PAETC.ORG/](http://paetc.org/)
- NATIONAL CLINICIANS CONSULTATION CENTER
  - [HTTPS://NCCC.UCSF.EDU/](https://nccc.ucsf.edu/)
- HIV CREDENTIALING FOR PHARMACISTS
  - [HTTPS://AAHIVM.ORG/HIV-PHARMACIST/](https://aa hivm.org/hiv-pharmacist/)

