



# Policies & Programs Needed to Ensure PrEP Access

Carl Schmid  
HIV+Hepatitis Policy Institute

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# DISCLOSURE OF CONFLICT OF INTEREST

HIV+Hepatitis Policy Institute receives funding from Gilead and Merck.





# PrEP Programs

## Coverage by various payers

- Private Insurance
- Medicaid
- Medicare

## Government Programs

- CDC
- Community Health Centers
- Ready, Set, PrEP

## Filling in the Gaps & Planning for the Future

- Role of Ryan White Program
- Congressional Legislation
- Funding



# Private Insurance: PrEP Coverage Requirements

**Affordable Care Act** requires non-grandfathered individual and small group plans to cover preventive services with no cost-sharing

**June 2019: U.S. Preventive Services Task Force (USPSTF)** issues "A" rating for PrEP for certain at-risk populations

**January 2021:** All Essential Health Benefit plans must cover PrEP w/o cost-sharing

# Federal Actions

## Included in [healthcare.gov](https://www.healthcare.gov) list of preventive services

- Some plans link to this list

## FAQ issued July 2021

- PrEP & ancillary services must be covered w/o cost-sharing
  - Enforcement begins after 60 days
- No restrictions on frequency; any medically appropriate limits must have expedient exceptions process
- If provider determines a certain Rx is “medically inappropriate” no cost sharing for its substitute

# Next Steps with Insurance Plan Requirement

## Publicize

- Consumers
- Regulators
- Insurance Companies
- Providers

## Enforce

- Drug Coverage
- Ancillary Services
- Exceptions Process
- Transparency

# 2021 Plan Review

## Spot check of formularies during Open Enrollment Period (Nov. 2020)

- Many plans in compliance
  - Offering at least 1 PrEP Rx w/o cost-sharing
- But several not & transparency issues

## Redid Spot Check (March & July 2021)

- Greater compliance, some transparency improvements, but still some violations

# CareSource – Georgia

<b>Drug Name</b>	<b>Drug Tier</b>	<b>Requirements / Limits</b>
TRUVADA	2	
DESCOVY	2	
<i>emtricitabine-tenofovir (tdf) oral tablet 200-300 mg</i>	0	





# Oscar 2021 Formulary

<b>Drug Name</b>	<b>Drug Tier</b>	<b>Requirements/Limits</b>
TRUVADA TAB 200-300 ( <i>emtricitabine-tenofovir disoproxil fumarate</i> )	2	QL (30 tabs / 30 days); \$0 copay for pre-exposure prophylaxis
DESCOVY TAB 200/25MG ( <i>emtricitabine-tenofovir alafenamide fumarate</i> )	2	QL (30 tabs / 30 days); Exception process available for \$0 copay when medically necessary for pre-exposure prophylaxis

# Examples of Plan Violations

	Medical Mutual (OH)	ConnectiCare (CT)	Kaiser Permanente (GA)
<b>Truvada:</b>	Not covered	Tier 4 (notes Generic Available)	Not covered
<b>Descovy:</b>	Tier 4	Tier 4	Tier 5
<b>Generic:</b>	Tier 4		Tier 2 (Preferred Generic)
<b>Preventive Drugs:</b>	Tier 5	Tier 0 <i>Separate Document listing all ACA Rx, PrEP not included</i>	ACA
<b>Formulary Updated:</b>	8/1/2021	7/1/2021	7/8/2021



# Violations & Transparency Issues

**Kaiser Permanente (WA):** Generic Truvada on Tier 1 and brand PrEP Rx's on Tier 4 , but one should be Tier P

**Kaiser Permanente (DC/MD/VA):** Generic Truvada on Tiers 1 and 3, Descovy on Tier 2, but one should be marked "PRV"

- Separate Document Listing Preventive Drugs, PrEP included

**Many plans place on high tiers,** but then if you click for additional information, \$0 cost sharing

**Lack of Consistency for Preventive Rx:** Tier 0, Tier 1, Tier 5, Tier 7, Tier P, \$0, "Prev", 'PRE" or "ACA"

# Anthem Drug Formulary

## Alphabetical Search

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

## Brand & Generic Name Search

[Start Over](#)

Please select a drug from the list below to continue.

- <sup>1</sup> [emtricitabine oral capsule 200 mg](#)
- <sup>4</sup> [emtricitabine-tenofovir df oral tablet 100-150 mg](#)
- <sup>NF</sup> [emtricitabine-tenofovir df oral tablet 133-200 mg](#)
- <sup>NF</sup> [emtricitabine-tenofovir df oral tablet 167-250 mg](#)
- <sup>1</sup> **[emtricitabine-tenofovir df oral tablet 200-300 mg](#)**

### Results

Brand Name <small>generic name</small>	Therapeutic Class <small>Sub-Class</small>	Dose/Strength	Status	Notes & Restrictions
<a href="#">emtricitabine-tenofovir df oral tablet 200-300 mg</a> <b>G</b>	<a href="#">"Antivirals" "ANTIRETROVIRAL COMBINATIONS"</a>	Tablet 200-300 MG	<b>TIER 3</b>	<a href="#">more info</a> <a href="#">more info</a> <a href="#">more info</a> <b>90</b>

# Next Steps for Compliance

Review plans to ensure at least 1 PrEP Rx \$0 cost-sharing

- And for others, if medically necessary

Ensure coverage of ancillary services w/o cost-sharing

Track beneficiary complaints

File complaints with Plans & State Insurance Regulators

Transparency of Preventive Services

# The Future

## Long-acting injectable, oral, & implants

- Most Likely will have to undergo a review by USPSTF
  - Even updates take over 1 year
  - Then plans have at least one year for compliance
- Will need updated federal guidance
  - Usually require plans to cover at least one form of preventive service w/o cost-sharing





# Medicaid & Medicare

## State Medicaid Programs cover PrEP

- But many states not expanded Medicaid to all low-income individuals

## Medicare

- PrEP Covered under Medicare Part D
- All ARV's must be covered
- Beneficiary cost-sharing applies



# Government Programs: CDC

## **Traditional CDC HIV Programs (\$755 m)**

- PrEP Outreach & Education
- No grant funding allowed for Rx's & Ancillary Services

## **Ending the HIV Epidemic (EHE) Programs (\$175 m)**

- PrEP Outreach & Education
- Ancillary Services
- No grant funding allowed for Rx's

## **Letter to CDC Leadership urging**

- Change to allow all HIV Grantees to Fund Ancillary Services
- Accounting of State EHE funding for PrEP



# Government Programs: 340B

## **STD Clinics, Ryan White Grantees, Community Health Centers & other clinics w/340B pharmacy**

- Utilize 340B program to buy drug at discount
- Collect income used to set up PrEP outreach programs & pay for ancillary services
- Income being reduced due to:
  - Reimbursement from free Rx program
  - Use of generic PrEP

# Government Programs: Community Health Centers

- 1,400 Health Centers across the country
- Serve uninsured, under insured, & insured
- Serve 1 in 11 people in the U.S.- almost 30 million
- 1 in 3 individuals living in poverty
- 37 percent clients Hispanic/Latino
- 22 percent clients Black/African American
- Many Ryan White Clinics are Community Health Centers
- Utilize 340B program to support PrEP & client's insurance/coverage

# Government Programs: Community Health Centers

## New EHE Funding for PrEP

- FY2020: \$54 million  
195 health centers in EHE jurisdictions that are also Ryan White clinics
  - FY2021: \$48 million  
108 health centers in EHE jurisdictions  
Awards start date: Sept 1
  - FY 2022: \$50 million Proposed  
140 health centers
- Total: \$152 million/443 health centers

# Government Programs: Ready, Set, PrEP

Free PrEP Rx for uninsured

Underutilized

No coverage of ancillary services

Clinics prefer to use 340B program to collect income

# Planning for the Future

Many Existing Gaps

New PrEP Options on the Horizon

Should the Ryan White Program be modified?

Congressional Bills

- Rep. Bonnie Watson-Coleman
- Sen. Tina Smith

Increased Funding for CDC & Community Health Centers

**THANK YOU!**

*Carl Schmid*  
*Executive Director*  
[cschmid@hivhep.org](mailto:cschmid@hivhep.org)  
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