

Enforcement Needed to Ensure Health Plan Compliance with HIV Preventive Drug Requirement

*NAIC Consumer Liaison Meeting
April 8, 2021*

*Carl Schmid
Executive Director*



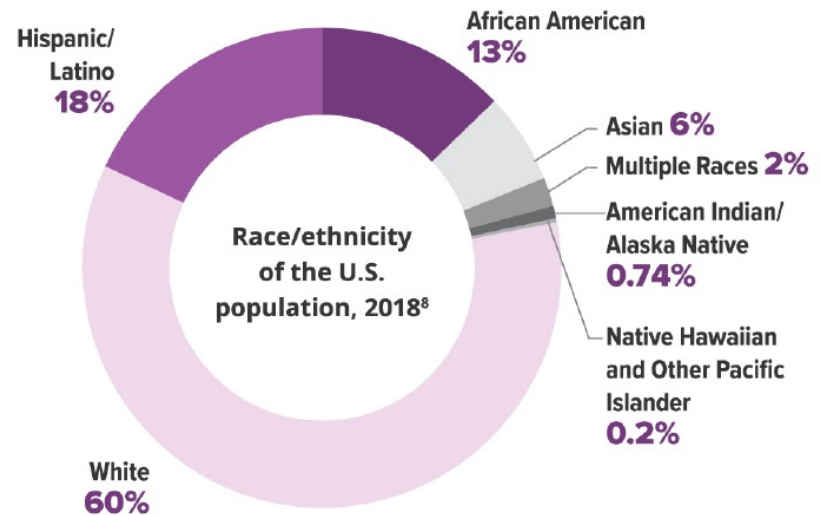
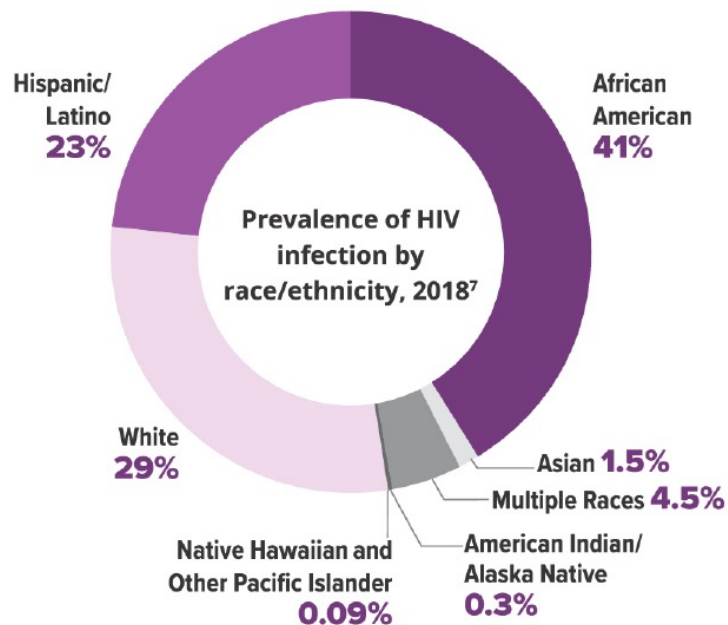
*Wayne Turner
Senior Attorney*



What is Pre-Exposure Prophylaxis (PrEP)?

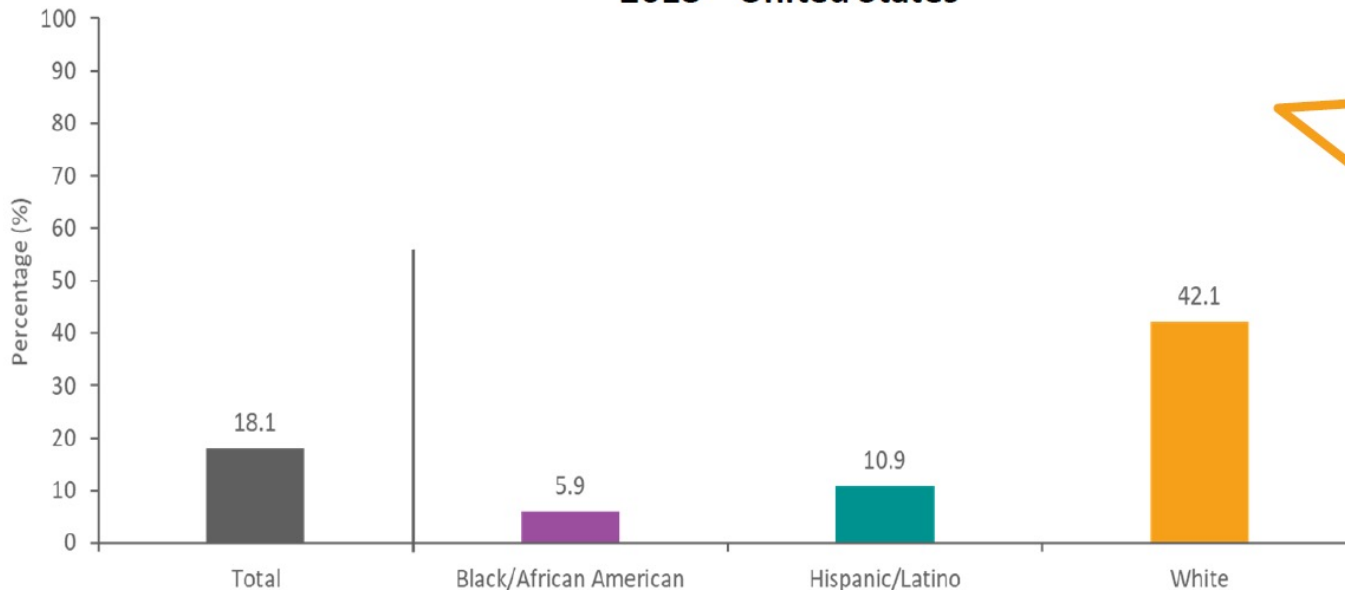
- Approved by FDA in 2012 and recommended by CDC in 2014 for HIV prevention
- Once daily medication regimen (three drugs now approved - Truvada, Descovy & Generic Truvada)
- Requires office visits, HIV & hepatitis B tests & other periodic lab tests monitoring liver and kidney function
- PrEP reduces the risk of contracting HIV by approx. 99%

Black and Hispanic/Latino communities are disproportionately affected by HIV.



Gaps in PrEP coverage are the highest among gay and bisexual men of color and transgender women.

PrEP Coverage among Persons Aged ≥ 16 Years, by Race/ethnicity
2018—United States



Just 18%

of the estimated > 1 million Americans who could benefit from PrEP are using the medication.

Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Race/ethnicity data were only available for 35% of persons prescribed PrEP in 2018. Number prescribed PrEP and PrEP coverage for race/ethnicity reported in the table were adjusted applying the distribution of records with known race/ethnicity to records with missing race/ethnicity. Different data sources were used in the numerator and denominator to calculate PrEP coverage.

<https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-prevention-and-care-outcomes-2018.pdf>

PrEP Coverage Requirements

- **Affordable Care Act** requires non-grandfathered individual and small group plans to cover ten Essential Health Benefits (EHB), including 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 EHB plans must cover PrEP w/o cost-sharing

Federal Actions

- Not included on healthcare.gov list of preventive services
 - Some plans link to this list
- PrEP ancillary services should also be covered w/o cost-sharing – example - colonoscopies
 - Interim Final Rule issued in December 2020 reiterates this
- FAQ on PrEP Pending

State Actions

NY:

Required Plan
Compliance beginning
January 2020

Further Guidance
requiring coverage
of ancillary services
w/o cost-sharing

CA:

Guidance to cover *all*
PrEP Rx w/o prior
authorization (state
law)

Includes
ancillary services
w/o cost-sharing

CO:

Regulation requiring
coverage of *clinically*
appropriate PrEP w/o
cost-sharing

Further Bulletin
encouraging
coverage of
ancillary services
w/o cost-sharing

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 2021)**
 - Greater compliance, some transparency improvements, but still some violations

Examples of Plan Violations

	Medical Mutual (OH)	ConnectiCare (CT)	Kaiser Permanente (GA)
Truvada:	Tier 4	Tier 4 (notes Generic Available)	Not listed
Descovy:	Tier 4	Tier 4	Tier 5
Generic:	Not listed		Tier 2 (Preferred Generic)
Preventive Drugs:	Tier 5	Tier 0 <i>Separate Document listing all ACA Rx, PrEP not included</i>	ACA
Formulary Updated:	3/1/2021	3/1/2021	3/10/2021

Transparency Issues

- **Kaiser Permanente (WA & DC):** Tier 4 for all 3 Rx, but should be Tier P
 - 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”, or “ACA”

Next Steps for Enforcement

- Regulators 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
 - Issue guidance or regulations
- Respond and track beneficiary complaints
- Prepare for new PrEP Rx's in the future
 - Long-acting injectable, oral, & implants

Thank you!

Wayne Turner

Senior Attorney

turner@healthlaw.org

Follow: [@NHeLP_org](https://twitter.com/NHeLP_org)



Carl Schmid

Executive Director

cschmid@hivhep.org

Follow: [@HIVHep](https://twitter.com/HIVHep)

