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U.S. PrEP Cost Analysis

Final Report

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Executive Summary

A major barrier to addressing the HIV epidemic in the United States is underutilization of pre-exposure prophylaxis (PrEP), an effective intervention for preventing HIV transmission among those individuals at greatest risk for infection. Only 30% of people with indications for PrEP are currently using the medication, and because of considerable disparities in PrEP uptake between racial and ethnic groups, underutilization is a more serious problem for Black and Hispanic individuals who meet eligibility criteria (Centers for Disease Control and Prevention, 2021a). Increased PrEP uptake is a key component of the strategy for Ending the HIV Epidemic in the U.S. (EHE). The EHE initiative aims to achieve a goal of 50% of PrEP-eligible people using PrEP by 2025. One potential barrier to PrEP utilization is its initial formulation as a daily oral medication that requires high adherence to be effective. Daily oral PrEP first became available in 2012. However, in late 2021, the U.S. Food and Drug Administration approved a long-acting, bimonthly injectable form of PrEP that may help improve adherence and effectiveness (Sopelsa et al., 2021). Other potential barriers are limited knowledge of the benefits of PrEP among eligible individuals and providers; an inadequate public health workforce to provide PrEP outreach, navigation, and adherence services; stigma; and costs. Brand-name PrEP medications may cost as much as \$22,000 per user per year, and the costs of required provider visits and laboratory services are generally not covered by programs that provide free PrEP medications. Yet, generic versions of daily oral PrEP medicines are available for as little as \$360 per person per year, and those now account for a large and growing share of PrEP prescriptions filled (Huang et al., 2022).

To support additional increases in PrEP uptake, Representative Watson Coleman reintroduced the PrEP Assistance Program Act in October 2021 to make PrEP easier to afford for populations at high risk of HIV (PrEP Assistance Program Act, 2019). The bill proposes establishment of a grant program for states, Indian tribal governments, federally qualified health centers, rural health clinics, and other local governments and community-based organizations (CBOs) to establish and maintain existing PrEP programs. Under the PrEP Assistance Program Act, expenses for PrEP drugs, ancillary services, outreach and navigation services, and adherence services would be covered.

To estimate the costs to achieve the EHE PrEP coverage goals, we created an Excel-based spreadsheet tool, the PrEP Cost Calculator (PrEP_CC), that estimates annual and cumulative costs through 10 years. PrEP_CC allows users to explore the impact on cumulative costs of changing any of the calculator's input values. For example, a user can explore the impact on costs of increases over time in using generic versus brand-name oral PrEP and in using long-acting versus daily oral PrEP. Our calculations include PrEP drug and ancillary costs for uninsured patients who are not already receiving free medications and ancillary services. We also include costs to provide support for a broad network of community health centers,

clinics, state and local health departments, and CBOs to set up and implement programs for PrEP that would provide outreach, navigation services, and adherence services to reach and engage individuals who are eligible for PrEP, especially those from groups with low current uptake.

We used published data on the number of people eligible for PrEP in 2019, the numbers using PrEP in 2021, the use of generic versus brand-name oral PrEP, and per-person PrEP drug and ancillary costs. However, limited data were available on the likely future uptake of long-acting formulations of PrEP and on the need for and costs to provide outreach and navigation services. Input values for these elements were informed by findings from interviews we conducted with six entities that provide PrEP to clients in areas across the United States.

Our analysis shows that a national PrEP Assistance Program that provides financial assistance for PrEP medications and ancillary services and allows for a substantial investment in expanding outreach and PrEP navigation services through a broad network of state and local providers and CBOs would cost about \$521.1 million in its first year of operation and \$6.18 billion to \$6.22 billion over a 10-year period. As additional information becomes available to further refine the program cost estimates, the HIV+Hepatitis Policy Institute can use the PrEP_CC to examine the impact on costs.

1. Introduction

The purpose of this report is to estimate the costs of expanding access to pre-exposure prophylaxis (PrEP) medications and services in the United States for individuals whose PrEP medications and related services are not covered by third-party payers, including private health insurers, Medicaid, and Medicare, or by federal programs, such as the 340B prescription drug discount pricing program and Ready, Set, PrEP, which provides free oral PrEP medications to eligible individuals. The PrEP cost estimates presented in this report also include costs for state and local jurisdictions, Health Centers, Ryan White grant recipients, sexually transmitted infection (STI) clinics, family planning centers, Indian Health Service clinics, and other local clinics and community organizations that provide outreach to the community and providers and support eligible individuals in obtaining and using PrEP.

1.1 Background

HIV remains a significant public health issue in the United States. More than 1.1 million Americans are living with HIV, and over 700,000 Americans have lost their lives to HIV since 1981 (HIV.gov, 2021). Additionally, the HIV epidemic is a significant economic burden, with an estimated lifetime treatment cost of \$1.08 million (undiscounted, 2019 dollars) for each person living with HIV (Bingham et al., 2021; discounted cost estimate of \$420,285¹). In 2019, the federal government announced the Ending the HIV Epidemic in the U.S. (EHE) initiative. This bold initiative aims for a 75% reduction in new HIV infections by 2025 and at least a 90% reduction by 2030 (HIV.gov, 2021).

A major barrier to addressing the HIV epidemic in the United States is underutilization of PrEP, which is a regimen of antiretroviral drugs that nearly eliminates virus acquisition (HIV.gov, 2021). Only 30% of people with indications for PrEP use it, and because of disparities in utilization by race and ethnicity, utilization is considerably lower among Black and Hispanic subpopulations than among White subpopulations (Centers for Disease Control and Prevention [CDC], 2021a; <https://ahead.hiv.gov>). In 2021, only 11% of Black individuals and only 20% of Hispanic individuals who were eligible for PrEP had been prescribed it (<https://ahead.hiv.gov>). In contrast, almost 80% of eligible White individuals had been prescribed PrEP medications (<https://ahead.hiv.gov>). There are also disparities by sex in 2021; about 12% of eligible females had been prescribed PrEP, while 34% of eligible males had been prescribed PrEP. Increased PrEP uptake is a key component of the strategy for EHE: the initiative aims for 50% of all PrEP-eligible people to use PrEP by 2025.

¹ Discounting of future costs adjusts for differential timing of when costs are incurred and allows costs to be compared from a baseline point in time (Basu & Ganiats, 2017). Bingham and colleagues (2021) applied a 3% annual discount rate to all future HIV medical costs to estimate discounted lifetime HIV medical costs of \$420,000 per person with HIV.

Although daily oral PrEP first became available in 2012, the high initial cost of PrEP medications and required ancillary services limited the medication's uptake. Generic versions are now available at a more affordable price of about \$30 per month, and new CDC guidelines recommend that clinicians discuss PrEP with all sexually active people (CDC, 2021b). However, several other barriers may affect PrEP prescription coverage and use. For example, lack of outreach and programs to cover the cost of ancillary services may be a factor. Additionally, shortages in the public health workforce make it challenging for state and local public health entities to provide navigation services for linking eligible people to PrEP and supporting adherence to PrEP (deBeaumont Foundation, 2021). Another potential barrier is the need to take oral PrEP daily. Long-acting forms of PrEP may help overcome this challenge. The first bimonthly injectable PrEP was approved by the U.S. Food and Drug Administration (FDA) in late 2021 (Sopelsa et al., 2021).

To help ensure access to PrEP for people who are eligible, Representative Watson Coleman reintroduced the PrEP Assistance Program Act in October 2021 to make PrEP easier to afford for populations at high risk of HIV (PrEP Assistance Program Act, 2019). The bill proposes to establish a grant program for states, Indian tribal governments, federally qualified health centers, rural health clinics, and other local governments and community-based organizations (CBOs) to establish and maintain existing PrEP programs. Under the PrEP Assistance Program Act, the following expenses necessary to support or establish a PrEP program would be eligible for reimbursement (if the act passes as drafted):

- Clinic and laboratory fees
- Office visits
- PrEP medications
- Testing required for people who use PrEP
- Sexually transmitted infections testing
- PrEP adherence services and counseling
- Outreach to the community of potentially eligible individuals and to providers for prescribing or providing education about PrEP

This report examines what it would cost to provide outreach and PrEP navigation to all individuals who are potentially eligible for PrEP use and to ensure that PrEP and associated medical services are available to and used by at least half of eligible individuals.

1.2 Study Overview

We estimated the costs of PrEP medications, ancillary services needed for people who use PrEP, and outreach and PrEP navigation costs needed to achieve the goals for PrEP use in the United States. First, using estimates of the number of people eligible for PrEP in the United States in 2019, we determined the numbers eligible by insurance type (private insurance, Medicare, Medicaid, and uninsured) and race and ethnicity (Black, Hispanic,

White, and other race). Second, we determined how many people were using PrEP in 2021 by insurance type and by race and ethnicity. We used these data to estimate increases in the number of people using PrEP that would be needed to achieve the EHE 5-year goal of half of those eligible for PrEP using PrEP.

Third, we compiled data on the following components needed to estimate the costs of expanded PrEP access and utilization:

- PrEP prescription drugs: brand name and generic, oral and long-acting
- Percentages of PrEP-eligible individuals who have insurance, type of insurance, and alternative strategies to provide PrEP for the uninsured, including purchases through the 340B Drug Pricing Program
- Ancillary services for people using PrEP, including provider visits, regular blood tests, and HIV and other STI testing
- Support to community health centers, clinics, and CBOs to provide or expand outreach services to the community and to providers about PrEP and to provide PrEP navigation and related services to support adherence to PrEP

To estimate the costs that would need to be covered to achieve the EHE PrEP coverage goals, we created an Excel-based tool that estimates annual and cumulative costs through 10 years, the PrEP Cost Calculator (PrEP_CC). PrEP_CC allows users to explore the impact on costs of changes in input values. For example, a user can explore the impact on costs of increases over time in the use of generic versus brand-name oral PrEP and in the use of long-acting versus daily oral PrEP.

2. Methods

We started by compiling the most recent data available on the number of people eligible for PrEP and the number of people using PrEP (CDC, 2021c; <https://aidsvu.org>). We then determined the distribution of those people across insurance categories and races and ethnicities. Costs for the following categories were applied to each subgroup and summed across subpopulations and cost categories: (a) PrEP drugs; (b) ancillary services, such as doctors' visits and laboratory services; and (c) support for a variety of entities to provide outreach and patient navigation and related services.

2.1 Data

The model required data on several categories of inputs, as described in this subsection. Data were needed to calculate the number of people eligible for PrEP use; the number of people who would use PrEP in each year, assuming the EHE PrEP goals are achieved within 5 years; and the cost per person to provide PrEP medications, ancillary services, outreach, and navigation services. In addition to searching the existing published and gray literature to identify data for analyzing costs, we also conducted six interviews with health centers, clinics, and one jurisdiction with expertise in providing PrEP. The interviews took place in the summer of 2022 and focused on how entities paid for PrEP drugs, ancillary services, and outreach for uninsured people; the payment mix of patients (e.g., Medicaid, Medicare, private insurance, or uninsured); entities' use of 340B revenue to help cover PrEP services; and approaches to and costs for outreach to individuals eligible for PrEP and navigation services to support enrollment in drug copay assistance programs and adherence services for PrEP. We also asked about the use of generic versus branded oral PrEP and whether long-acting PrEP was being used.

2.1.1 Number of People Eligible for PrEP

We attempted to identify a source that provided the number of people who are eligible for PrEP by transmission group (e.g., men who have sex with men [MSM], heterosexuals, and people who inject drugs) by insurance status, and by race and ethnicity. However, no single source had data on PrEP eligibility broken down by transmission group, insurance status, and race and ethnicity. Additionally, to estimate the number of people with Medicaid coverage, we needed state-level data to account for states that had expanded Medicaid services. To allocate the number of people eligible for PrEP across all categories of interest, we combined several sources of data in a two-step process.

Step 1: Determine the PrEP-Eligible Population by Transmission Group

To estimate the size of the PrEP-eligible population by transmission group, we started with the data that were calculated in 2015 (Smith et al., 2018), which allocated the PrEP-eligible population across states and transmission groups. We applied the 2015 percentage

allocations by state and by transmission group to the 2019 PrEP-eligible population (U.S. Department of Health and Human Services [HHS], 2019) to determine the number of people eligible for PrEP in each state in 2019 by transmission group. The total number of people eligible for PrEP in 2019 was 1,216,210 (CDC, 2021b).

Step 2a: Determine the PrEP-Eligible Population by Insurance Status

Next, we determined the insurance status of the PrEP-eligible population. We employed separate methods for each of the four insurance categories: Medicare, Medicaid, uninsured, and privately insured. For Medicare, we determined the number of PrEP-eligible individuals aged 65 or older and assumed they all have Medicare as their primary payer. Because the oldest age category from America's HIV Epidemic Analysis Dashboard (AHEAD) data was people aged 55 or older, we estimated the number in the 65 or older age group by applying the age percentage breakdown from data on age at HIV diagnosis (CDC, 2020a). For Medicaid, we determined the percentage of PrEP-eligible individuals by transmission group that was below the federal poverty level (CDC, 2019, 2020b, 2021d) and applied those percentages to the results from Step 1 if the state had undergone a Medicaid expansion (Medicaid.gov, 2021). For the uninsured, from CDC data, we determined the percentage of each transmission group that did not have insurance and applied those percentages to the data from Step 1 (CDC, 2019, 2020b, 2021d). Finally, for the privately insured, we used the overall numbers from Step 1 and subtracted the Medicare, Medicaid, and uninsured populations from the total PrEP-eligible population. Our estimates suggest the following approximate distribution of people who are eligible for PrEP across insurance categories: 2.4% Medicare, 23% Medicaid, 55% private insurance, and 20% uninsured.²

Step 2b: Determine the Number of People Eligible for PrEP by Race and Ethnicity

To estimate the number of people eligible for PrEP for each race and ethnicity group and by insurance status, we started with surveillance estimates of the number of people eligible for PrEP by race and ethnicity in 2019, as reported in HIV surveillance data (CDC, 2021c). We estimated the percentage of each race and ethnicity group in each of the four insurance categories using data from the Kaiser Family Foundation (2020). Those data indicated the representation of each race and ethnicity group in the payer population. We compared these proportional representations with representation in the U.S. adult population to estimate percentages of each race and ethnicity group in each insurance category so that the total closely matched our allocation from Step 2 of the number of people eligible for PrEP by insurance category. Our estimated allocations across insurance category vary by race and ethnicity, as shown in the PrEP_CC "Cohort_R_E" tab. For example, we estimate that the percentage of the PrEP-eligible population covered by Medicaid is 30% for Black, 22% for Hispanic, 15% for White, and 20% for other races. For the uninsured category, the

² Sums to greater than 100% because of rounding.

analogous allocations are 18%, 31%, 17%, and 13%, respectively, for Black, Hispanic, White, and other race subpopulations. Our analyses assume these allocations for the full period. Although our analysis used the 2019 surveillance data to anchor the estimates, we allow for growth of 0.54% per year in the number of people eligible for PrEP (World Bank, n.d.). Hence, we assume that 1,236,020 people are eligible for PrEP in 2022, and the numbers will increase modestly over time, to 1,297,400 people by 2031.

2.1.2 Number of People Using PrEP

To determine the number of people using PrEP across the four subpopulations, we started with surveillance data on the number of people using PrEP by race and ethnicity (<https://aidsvu.org>). These data indicate that 362,844 people were using PrEP in 2021: 50,498 Black, 62,131 Hispanic, 234,160 White, and 16,055 other race. We further allocated the individuals by race and ethnicity across transmission groups (assumed, based on the distribution between males and females from AHEAD) (HHS, 2019) and across insurance categories. To estimate the distribution across insurance categories, we used estimates reported in Chan and colleagues (2020) of the payment methods for PrEP in the United States. Using those findings for September 2015 through August 2016, we calculated the distribution of people using PrEP across insurance categories, as follows: 4% Medicare, 12% Medicaid, 78% private insurance, and 6% uninsured. These allocations assume mutually exclusive primary payers and do not consider other federal insurance programs, such as TRICARE. Of note is that 78% of people using PrEP had private insurance, whereas we estimated that 55% of people eligible for PrEP had private insurance. Additionally, although we calculated that 23% of those eligible for PrEP were covered by Medicaid and another 20% were uninsured, much lower percentages of people using PrEP fell into those categories.

To estimate the number of people using PrEP over time as the EHE PrEP goals are achieved, we considered two scenarios. First, we assumed that the number of people in each insurance category would increase linearly over 5 years to achieve the goal of 50% of people in each insurance category covered by PrEP. In Years 6–10, small annual increases beyond the 5-year goal reflect assumed population increases. Because a much lower percentage of eligible people with Medicaid and no insurance were using PrEP at the start in 2022, the numbers of people using PrEP in these categories increase more rapidly than the numbers with private insurance and Medicare. Under this scenario, we estimated that 653,217 people would be using PrEP in 2027.

Second, we assumed the EHE PrEP goals would be achieved by focusing on closing racial and ethnic gaps in PrEP use to achieve a goal of having 50% of eligible people in each race and ethnicity group using PrEP after 5 years. This assumption leads to rapid increases for Black, Hispanic, and other races, but because the White subpopulation starts at 78%, the PrEP goal is already being met for them. However, there was room for improvement in the

uninsured category among the White subpopulation, so we allowed the numbers using PrEP to grow until 50% of those in the White uninsured subpopulation were using PrEP. At the same time, we held constant the numbers of insured White people using PrEP for the first 5 years, then allowed those numbers to increase in line with the assumed population growth rate. This approach resulted in a larger number of people using PrEP by 2027 than the first scenario did. We estimated that 723,970 people would be using PrEP in 2027 under Scenario 2 (vs. 653,217 in Scenario 1).

2.1.3 Inputs for Cost, Proportions Using PrEP, and PrEP-Related Programming Costs

To estimate what it would cost to achieve the EHE goals for PrEP use, we also needed data on the cost inputs and percentages of people using each type and formulation of PrEP. In this section, we briefly describe the sources for each input value used in the calculations. Input descriptions, values, and sources are summarized in **Table 2.1**.

Table 2.1 U.S. PrEP Cost Model Inputs

Input	Description	Value	References
Time horizon	Costs are shown annually and cumulatively to examine any time horizon of interest through 10 years.	Up to 10 years	N/A
Cost valuation	Costs are shown in 2021 dollars; costs from earlier years were adjusted using the medical care component of the Consumer Price Index.	Varies	U.S. Bureau of Labor Statistics, n.d.
Number of PrEP-eligible individuals by risk transmission group and payer: Distributed 2019 CDC AHEAD data across states and transmission groups using 2015 estimates of the number of adults with indications for PrEP by jurisdiction and risk transmission group. Derived the numbers of PrEP-eligible individuals by payer type using data from AHEAD, CDC surveillance, National HIV Behavioral Surveillance cycle 5, and 2021 Medicaid expansion status by state. Estimated the numbers of PrEP-eligible individuals by race and ethnicity using CDC surveillance data.			
Total number of PrEP-eligible individuals	Estimated total number of PrEP-eligible individuals in 2019 based on CDC AHEAD data.	1,216,210	CDC, 2019, 2020a, 2020b, 2021a, 2021b, 2021c; HHS, 2019; Medicaid.gov, 2021; Smith et al., 2018
Annual population growth rate	Used the average U.S. population growth rate from 2016 to 2020 to estimate growth in the PrEP-eligible population over the time horizon of interest.	0.54%	World Bank, n.d.

Input	Description	Value	References
PrEP drug costs: Annual cost per person for PrEP drugs, assuming 100% adherence. Includes a gradual increase in PrEP uptake to 50% of eligible individuals after 5 years. Baseline analyses assume that the proportion of people using generic daily oral PrEP versus brand-name daily oral PrEP will increase slightly over time to a maximum of 75% of oral PrEP users; also assume shift to use of long-acting PrEP for 20% of PrEP users by Year 5 and reaching 80% long-acting PrEP by Year 10. Assumes 5% of the uninsured will require drug cost coverage, and the price for these drugs are based on 340B prices. Assume that 95% of the uninsured and all with private and Medicaid insurance will have no costs for PrEP drugs. For the uninsured, those costs will be covered by insurance, manufacturers' plans, clinics' 340B resources, or state or other programs. Assume 10% of uninsured PrEP users will be insured with a health clinic's or health center's support; assume 50% of the uninsured will need assistance for ancillary costs, including the 5% who require drug coverage. Assume 5% of those with Medicare will need assistance to cover 10% of their drug and ancillary costs. Assume no copay or other insurance assistance is needed for the privately insured and those on Medicaid.			
Brand-name oral PrEP	Annual drug costs per person for brand-name daily oral PrEP. Weighted average of TDF and TAF prices; 79% assumed to use TAF.	\$16,193	U.S. Department of Veterans Affairs, 2022, adjusted to 2021\$
Generic oral PrEP	Annual drug costs per person for generic daily oral PrEP.	\$360	Davis et al., 2022; Killelea & Horn, 2021
Brand-name long-acting PrEP	Annual drug costs per person for brand-name long-acting PrEP. Assumes \$3,700 per dose.	\$22,200	Jones & Torres, 2022; U.S. Department of Veterans Affairs, 2022 (\$22,000)
340B pricing, oral PrEP	Annual 340B drug costs per person for daily oral PrEP.	\$5,770	Bonacci et al., 2022, adjusted to 2021\$
340B pricing, long-acting PrEP	Annual 340B drug costs per person for long-acting PrEP.	\$17,072	Assumed 23.1% discount
PrEP ancillary costs: Annual PrEP costs per person for required PrEP ancillary services.			
PrEP program costs	Annual cost per person using PrEP for clinic visits and required laboratory testing.	\$1,977	Davis et al., 2022; Shrestha et al., 2022
Outreach and PrEP navigation costs: Annual costs for community health centers, clinics, CBOs, and other grantees to provide outreach and navigation support to increase PrEP use. Includes costs for the workforce needed to provide adherence services as part of PrEP navigation. Assume outreach and PrEP navigation costs are fixed costs that are incurred annually. Costs are allocated as follows: \$325,000 to 75% of 1,373 U.S. health centers; \$325,000 to each of 500 Ryan White state, city, and clinic grantees that are 340B providers; and \$125,000 per year to an estimated 1,200 entities that may provide PrEP outreach and navigation services, including, but not limited to, CBOs, sexually transmitted infection clinics, family planning centers, and Indian Health Service clinics. The costs would be offset by anticipated annual allocations of \$172 million to the U.S. Health Resources and Services Administration's Bureau of Primary Health Care, which funds health centers in medically underserved communities.			
HIV incidence: HIV incidence for people using PrEP and for PrEP-eligible people who do not use PrEP was used to estimate the potential impact of PrEP in the number of cases of HIV.			
HIV incidence among people not using PrEP	Estimated HIV incidence among people not using PrEP for men who have sex with men, heterosexuals, and people who inject drugs.	3.0%	CDC, 2021c; Mera et al., 2019 (3.1%)
Estimated HIV incidence among people using PrEP	Estimated HIV incidence for people who use PrEP.	1.72%	Davis et al., 2022

340B = 340B Drug Pricing Program; AHEAD = America's HIV Epidemic Analysis Dashboard; CBO = community-based organization; N/A = not applicable; PrEP = pre-exposure prophylaxis; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate.

Annual PrEP Drug Costs

PrEP drug costs are based on the April 2022 Federal Supply Schedule daily drug acquisition cost for Truvada and Descovy (U.S. Department of Veterans Affairs, 2022), converted to an annual cost. We used the price of \$3,700 for injectable PrEP (Apretude), which was the list price initially reported for Apretude when it was approved in 2021. We assumed generic oral PrEP is \$360 per year based on the monthly wholesale acquisition price of \$30 for emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) (Redbook, n.d.). The 340B price for oral branded PrEP was based on the Bonacci et al. (2022) weighted average of 340B prices for 2018 for Truvada, Descovy, and generic FTC/TDF. Although generic PrEP was included in the weighted average, its use was relatively low and price still relatively high in 2018.

Percentage of people using each brand or formulation

The baseline assumptions for the percentages using daily oral PrEP are 48% generic and 52% brand name, based on findings reported by Huang and colleagues (2022), who analyzed PrEP prescriptions with payment data for Quarters 1–3 of 2021. Because FDA had not yet approved long-acting PrEP at that time, Huang and colleagues did not observe use of long-acting PrEP. Our baseline analysis assumes that the use of daily oral PrEP will decline over time, with an increasing reliance on long-acting PrEP. We assume that use of long-acting PrEP will increase to 20% by Year 5 and to 80% by Year 10, as payer coverage improves and populations that have not yet been reached by oral PrEP choose newer long-acting formulations. Use of generic oral PrEP will increase over time to account for 75% of oral PrEP use by Year 5.

Percentage of people with costs for PrEP or ancillary services

Data on the percentage of people obtaining free PrEP medications and ancillary services under the 340B program are limited. Although we attempted to obtain data on these percentages through conversations with representatives of various entities that provide PrEP services (see subsection 3.3), use of 340B and other approaches to cover PrEP medication and related costs for people who are uninsured varies from place to place. Our calculations assumed that 10% of uninsured users would receive private insurance coverage through the support of local PrEP providers, and as a result, their PrEP drug and ancillary costs would be covered. We further assumed that 40% of the uninsured will receive free PrEP drugs and ancillary services under 340B or other programs or grant mechanisms, including Ready, Set, PrEP. Although up to 200,000 individuals could receive free PrEP drugs under the Ready, Set, PrEP program, use of the program has been limited thus far. The Office of Infectious Disease and HIV/AIDS Policy reported that Ready, Set, PrEP had nearly 5,700 enrolled or conditionally enrolled participants as of July 2022, with almost 27,000 bottles of PrEP distributed between December 2020 and July 2022 (personal communication, September 12, 2022). Our assumptions about coverage for the uninsured suggest that 45% of uninsured individuals who use PrEP will need to have ancillary costs covered; an additional

5% will need both drugs and ancillary cost coverage. These assumptions were informed by responses provided by interview respondents.

The costs of PrEP drugs and ancillary services may have been a larger barrier to PrEP uptake prior to July 2021, when the U.S. Departments of Labor, Health and Human Services (HHS), and the Treasury clarified that all Affordable Care Act (ACA)-compliant health insurance plans (including Marketplace, individual, and small group plans) must provide coverage, without cost-sharing for at least one PrEP drug, as well as for ancillary services, such as HIV testing, STI screening and counseling, PrEP adherence counseling, and office visits associated with PrEP. However, grandfathered and other non-ACA-compliant health insurance plans are exempt, and individuals with these plans may continue to incur cost-sharing. Additionally, people taking PrEP with Medicare coverage may still face cost-sharing for PrEP drugs and ancillary services.

Annual PrEP Ancillary Costs

Additional costs required for individuals taking PrEP were from Shrestha and colleagues (2022) and included PrEP-related costs for clinic visits and required laboratory testing. We used the average program cost between the two sites included in the study: Chicago, Illinois, and the District of Columbia. Average costs were \$1,797 per patient in 2017 dollars, which we inflated to \$1,977 in 2021 dollars for the analysis.

Annual Costs to Support PrEP Outreach and Navigation

We explored several sources of costs for outreach and PrEP navigation but found limited information that was specific to PrEP or that directly analyzed costs to provide outreach services. Patient navigation costs in the published literature, including analyses of patient navigation costs, focus on people with HIV, such as providing linkage to HIV care (Shade et al., 2021) and improving patient retention in HIV care (Maulsby et al., 2017). To obtain better information on the costs specifically related to PrEP outreach and navigation, we reached out to two health centers, three clinics, and a jurisdiction to discuss how they handled outreach and navigation services for PrEP. Their responses informed the assumptions we used to estimate outreach and navigation costs for PrEP. Those assumptions are summarized in **Table 2.1**.

Several existing funding sources may be used to support a portion of outreach and navigation services for PrEP (NASTAD, 2022). For example, health departments that have received CDC's Integrated HIV Surveillance and Prevention awards may use those funds to provide information about PrEP and to support personnel conducting PrEP-related activities (CDC, 2021e). Additionally, the Health Resources & Services Administration (HRSA) has provided grants averaging approximately \$325,000 to each of 366 health centers to cover PrEP medications and ancillary services and to strengthen community partnerships with

Ryan White HIV/AIDS Program awardees to ensure better connections between prevention and treatment services (Health Center Program, 2022; HHS, 2022b).

Another ongoing effort to expand PrEP services is CDC's EHE: Scaling Up HIV Prevention Services in Sexually Transmitted Disease (STD) Specialty Clinics (CDC, 2022). Since 2019, CDC has funded 22 jurisdictions to expand EHE efforts through STD clinics (CDC, 2022). Awardees were able to build capacity to offer PrEP and build community connections to support linkages across the HIV prevention and treatment spectrum (CDC, n.d.), receiving up to \$800,000 for a single year's effort. For example, Baltimore City Health Department expanded late-night shifts for its mobile testing outreach, and Baton Rouge's Open Health Care Clinic hired additional nursing staff to support PrEP enrollment (CDC, n.d.). Federal funding is not the only option for paying for expanded PrEP services; 340B providers can cover the costs of PrEP-related outreach and patient navigation services by using their 340B revenues. Interview respondents described a variety of ways of increasing outreach and navigation services for PrEP, noting that additional funding that could be used flexibly to support expanding outreach and PrEP navigation would be most beneficial. Malebranche and colleagues (2022) made a similar argument, indicating that partnerships are needed between public and private entities to allow eligible individuals to obtain PrEP in traditional as well as non-traditional settings, ranging from clinics to telemedicine to mobile services.

We used information from the interview respondents and from a review of available funding opportunities that could be used for expanding PrEP outreach and navigation services to estimate the additional funding needed for PrEP outreach and related services. Most currently funded community health centers would also require funding of \$325,000 per center per year to support their expansion of PrEP outreach and related services. In 2021, there were 1,373 health centers in the United States (HRSA, n.d.-a). Our analysis assumes that 75% of these health centers, or approximately 1,030, will require ongoing financial support to implement or expand PrEP outreach and navigation and adherence services. This funding could be used to hire and train new staff, increase hours and training for existing staff, and implement focused media campaigns. Our assumptions are that in addition to 500 Ryan White recipients each needing \$325,000 per year to expand and sustain PrEP-related outreach and navigation, this same level of funding—\$325,000—is needed for 500 of the 2,131 cities, states, clinics, and CBOs that receive funding as Ryan White HIV/AIDS recipients or sub-recipients to meet the EHE goals for PrEP (HRSA, n.d.-b).

However, other health clinics and CBOs may also need support for outreach and expanding PrEP navigation and adherence if the EHE goals are to be met. For example, STI clinics, family planning centers, CBOs, and Indian Health Service clinics serve as trusted sources of health information and services for many people who are eligible for PrEP. Although these clinics and organizations can rely on other sources of funding for some of the PrEP outreach and navigation services they provide (e.g., STI clinic funding for EHE), our interview respondents suggested that additional funding is needed to expand and sustain PrEP-related

services. Because we were unable to obtain a reliable count of the total number of such clinics and organizations, we assumed that 1,200 entities would each require funding of \$125,000 per year to support hiring and retention of staff specifically working on PrEP and to allow for media buys. This number—1,200—is a conservative, yet realistic estimate of the number of such clinics and organizations, given that there are more than 2,500 STD clinics affiliated with a local health department in the United States (Meyerson et al., 2019). The estimate of \$125,000 is an average estimated award amount considering that median annual wages (not including benefits) for health education specialists were \$60,600 in 2021 (U.S. Bureau of Labor Statistics, 2022). This level of funding could support recipients to hire one to two additional full-time equivalent patient navigators and cover additional outreach-related costs. Additionally, STI clinics can continue to utilize revenues generated by the 340B program to conduct PrEP activities, including purchasing PrEP medications. According to HRSA, STI clinics purchased \$871 million in prescription drugs through the 340B program in 2021.³

The amount for outreach and PrEP navigation excludes anticipated annual allocations of \$172 million per year to support the Health Center Program at HRSA. This is the amount requested in the president’s fiscal year 2023 budget (Dawson & Kates, 2022). Health centers are an important setting for identifying HIV-negative individuals who have indications for PrEP and providing navigation for PrEP services (Health Center Program, n.d.). To calculate the total estimated cost of outreach and PrEP navigation, we summed the assumed funding needs across all entities (e.g., Ryan White cities, states, and clinics; community health centers; and other clinics and CBOs) and then subtracted \$172 million each year to reflect additional funding for PrEP services that some of the community health centers are expected to receive, even in the absence of additional PrEP Assistance Program funds.

2.2 Cost Calculations

We calculated the cost for each cost component by insurance category. **Table 2.2** shows the cost components included in baseline calculations. Cost calculations for Medicaid and private insurance categories assume no costs will be incurred for PrEP drugs or ancillary services for beneficiaries who use PrEP. For the Medicare category, the baseline analysis assumes that 5% of PrEP users require financial assistance to cover 10% of their drug and ancillary costs. For the uninsured category, the baseline analysis includes PrEP drug costs for 5% of the uninsured. Costs are also included for ancillary services for 50% of uninsured people who use PrEP.

As noted in Section 2.1, a lump sum of outreach and PrEP navigation costs was assumed to be needed in each year to support the expansion of the PrEP navigation and outreach

³ See <https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases>.

workforce across community health centers; STI clinics; Ryan White cities, states, and clinics; and other CBOs. Such expanded services are likely to be needed especially in areas with lower current levels of staffing and resources to support PrEP outreach and navigation.

Table 2.2 Funding Needs for PrEP, by Insurance Category

Cost Category	Ancillary Services				
	PrEP Prescription Drugs	Ongoing Provider Visits	Regular Blood Tests for HIV and Other STI Testing	Other Medical Services	Support for Outreach and Navigation
Insurance Category*					
Medicare†	X	X	X	X	X
Medicaid‡					X
Private					X
Uninsured§	X	X	X	X	X

PrEP = pre-exposure prophylaxis; STI = sexually transmitted infection.

* In July 2021, when the U.S. Departments of Labor, Health and Human Services, and the Treasury clarified that all Affordable Care Act (ACA)-compliant health insurance plans (including Marketplace and individual and small-group plans) must provide coverage, without cost-sharing, of at least one PrEP drug, as well as for PrEP ancillary services, such as HIV testing, STI screening and counseling, PrEP adherence counseling, and office visits associated with PrEP. However, grandfathered and other non-ACA-compliant health insurance plans are exempt, and individuals with these plans may continue to incur cost-sharing. Also, not all plans are compliant with this rule.

† Medicare enrollees may still face cost-sharing for PrEP drugs and ancillary services.

‡ Not all states have expanded Medicaid under ACA, so there are differences at the state level as to who is eligible for Medicaid.

§ Several programs for the uninsured help eliminate cost-sharing for people on PrEP. Gilead Advancing Access and ViiVConnect (manufacturer assistance programs) assist with the costs of branded medications but do not cover laboratory or ancillary services. Ready, Set, PrEP (federal PrEP program) covers brand-name oral PrEP but does not cover laboratory or ancillary services. In addition, there are some state PrEP assistance programs. Nearly all cover PrEP drug costs and most cover ancillary services. Finally, 340B PrEP programs enable purchase of PrEP drugs at a discount with incentives for prescribing brand-name drugs. These revenues may be used to cover laboratory services, clinic visits, outreach and PrEP navigation, and linkage-to-care services.

References: Gilead Sciences, 2021; HIV.gov, 2022; ; HRSA, 2017; NASTAD, n.d.; U.S. Department of Labor et al., 2021.

3. Results

In this section, we summarize findings from the baseline analysis of PrEP costs for 2022 and cumulatively over 10 years (i.e., through 2031). Because PrEP_CC provides flexibility for altering input values and assumptions, the HIV+Hepatitis Policy Institute and its partners can use the calculator to explore the impact of changing input values, especially refining input values to accurately depict the landscape for expanding PrEP drugs and services coverage in the United States as more information becomes available about how the use of oral versus long-acting PrEP changes over time, how the prices for each PrEP drug formulation changes over time, and the impacts of changes in manufacturers’ participation in the 340B program on entities’ needs for additional external support for outreach and PrEP navigation.

We estimated that the number of people using PrEP in 2022 is approximately 423,032, which represents a 48% increase over the 2019 number of 284,464 (**Table 3.1**). The White subpopulation accounts for the largest share of those using PrEP in 2022 (56%); the Black subpopulation accounts for the next-largest share (20%), followed by the Hispanic (19%) and other race (6%) subpopulations.

Table 3.1 Estimated Number of People Using PrEP, by Payer Type and Race and Ethnicity: 2022

Number of People Using PrEP	Black	Hispanic	White	Other Race	Total
Medicare	2,572	2,705	9,764	787	15,828
Medicaid	17,144	12,012	27,179	3,841	60,177
Private insurance	53,414	52,857	183,523	17,923	307,718
Uninsured	9,817	11,486	15,738	2,270	39,310
All payer types	82,947	79,060	236,205	24,821	423,032

PrEP = pre-exposure prophylaxis.

Our calculations allowed for increases in the number of people using PrEP in each year to achieve the EHE PrEP goals by 2027. By 2031, we estimated that 739,740 people would be using PrEP. In addition, by the end of 2031, we found an increase in the share of Black people using PrEP to 33% with a similar share of 34% for White people. The share of Hispanic people was 22%, with the remaining share for other races. **Table 3.2** shows the cumulative number of person-years of PrEP use estimated for the 10-year period from 2022 through 2031 by payer type and by race and ethnicity.

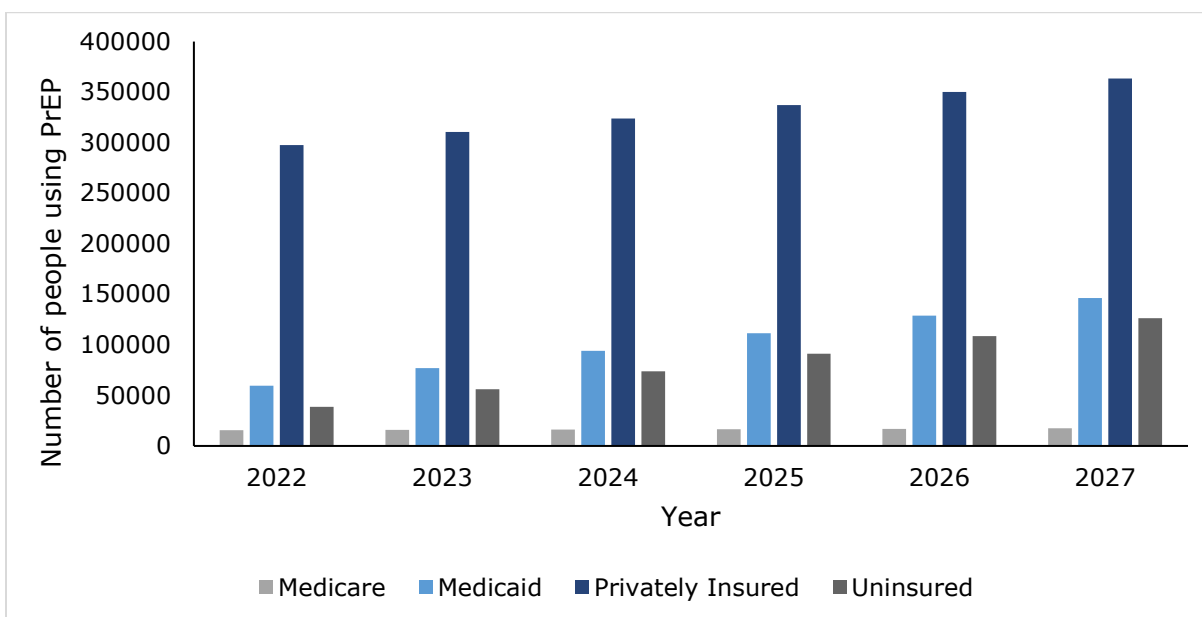
Table 3.2 Number of Person-Years of PrEP Use, by Payer Type and Race and Ethnicity: 2022–2031

Number of Person-Years of PrEP Use	Black	Hispanic	White	Other Race	Total
Medicare	42,309	31,210	98,173	12,045	183,739
Medicaid	570,331	290,094	273,268	108,376	1,242,069
Private insurance	1,025,073	678,234	1,845,198	368,540	3,917,044
Uninsured	340,789	392,447	230,343	69,764	1,033,341
All payer types	1,978,502	1,391,984	2,446,982	558,725	6,376,193

PrEP = pre-exposure prophylaxis.

A large part of the growth in the number of people using PrEP is among people with Medicaid or those with no insurance. **Figure 3.1** shows that the numbers of people using PrEP who are covered by Medicaid or who have no insurance are estimated to roughly double from 2022 through 2027, helping to close the gap on needed coverage for people in those insurance categories.

Figure 3.1 Number of People Using PrEP, by Year and Payer Type in Years 1–6

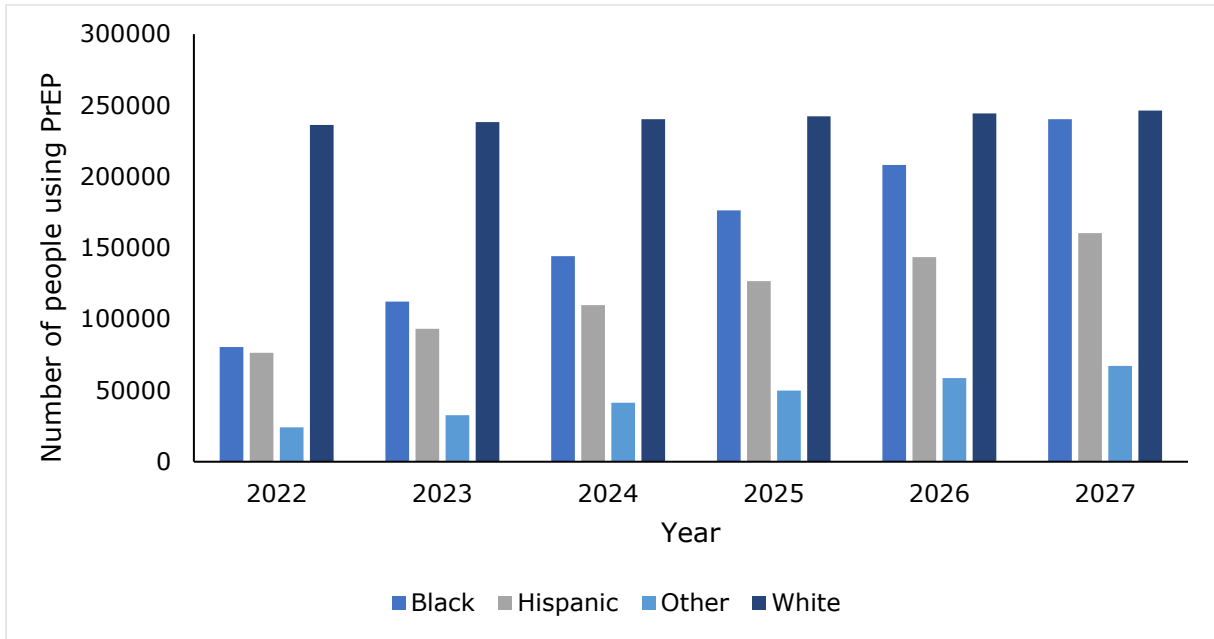


PrEP = pre-exposure prophylaxis.

Figure 3.2 shows the estimated numbers of people using PrEP by race and ethnicity from 2022 through 2027. As shown in the figure, achieving a goal of having half of those eligible for PrEP using PrEP will require substantial growth in the number of Black people using PrEP. The numbers of PrEP users are also expected to increase considerably for the Hispanic and other race subpopulations, while the size of the White subpopulation, among which 78% of

those eligible for PrEP are using PrEP in 2022, is estimated to remain about the same through 2027.

Figure 3.2 Number of People Using PrEP, by Year and Race and Ethnicity in Years 1–6

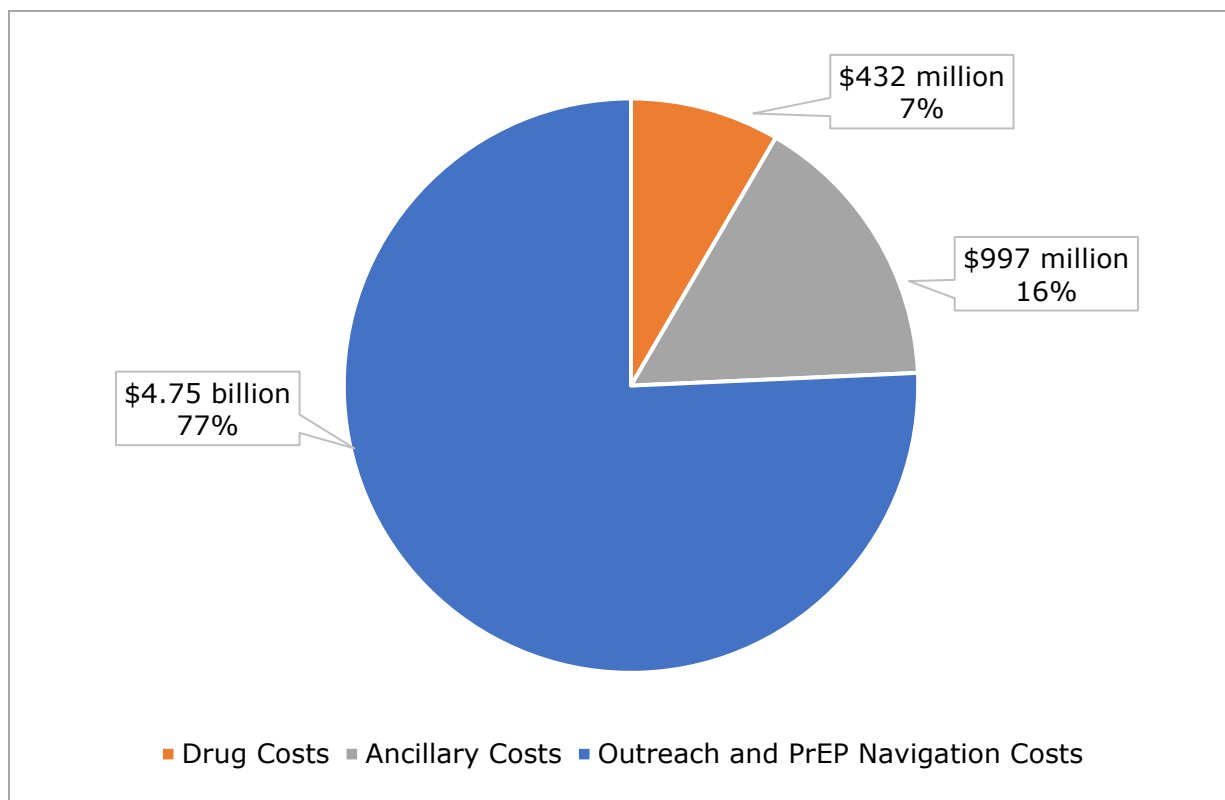


PrEP = pre-exposure prophylaxis.

3.1 PrEP Costs

As shown in **Figure 3.3**, costs to cover outreach and PrEP navigation services account for the largest portion of total estimated PrEP costs through 10 years (76%). Ancillary costs account for the next-largest portion (16%), followed by drug costs (8%).

Figure 3.3 Estimated Allocation of Total PrEP Costs over 10 Years, by Cost Category



PrEP = pre-exposure prophylaxis.

3.1.1 PrEP Costs by Payer Type

The total estimated PrEP cost was \$533 million in 2022, as shown in **Table 3.3**. Eighty-nine percent of this estimated cost is to support health entities to provide outreach and PrEP navigation services to populations that need it. Seven percent of costs are for ancillary services, and the remaining 4% is to cover drug costs.

Table 3.3 Estimated PrEP Costs, by Category and Payer Type: 2022

By Payer	PrEP Drugs	Ancillary Services	Subtotal: Drugs + Ancillary Services	Outreach and PrEP Navigation	Total
Medicare	\$739,582	\$153,215	\$892,798	N/A	
Medicaid	\$0	\$0	\$0	N/A	
Private insurance	\$0	\$0	\$0	N/A	
Uninsured	\$6,771,247	\$38,274,405	\$45,045,652	N/A	
All payer categories	\$7,510,830	\$38,427,620	\$45,938,450	\$475,168,750	\$521,107,200

N/A = not applicable; PrEP = pre-exposure prophylaxis.

As shown in **Table 3.4**, the cumulative estimated cost over 10 years is approximately \$6.18 billion. The cost to cover drugs and ancillary services for the uninsured is \$1.42 billion. Outreach and PrEP navigation costs account for 77% of the cumulative total.

Table 3.4 Cumulative Estimated PrEP Costs, by Category and Payer Type over 10 Years

By Payer	PrEP Drugs	Ancillary Services	Subtotal: Drugs + Ancillary Services	Outreach and PrEP Navigation	Total
Medicare	\$10,626,990	\$1,669,267	\$12,296,257	N/A	
Medicaid	\$0	\$0	\$0	N/A	
Private insurance	\$0	\$0	\$0	N/A	
Uninsured	\$421,628,704	\$995,028,874	\$1,416,657,578	N/A	
All payer categories	\$432,255,694	\$996,698,141	\$1,428,953,835	\$4,751,687,500	\$6,180,641,335

N/A = not applicable; PrEP = pre-exposure prophylaxis.

3.1.2 PrEP Costs by Race and Ethnicity

When we examined costs by race and ethnicity and allowed for PrEP use to increase the most in the subpopulations that were most underrepresented among current PrEP users, we estimated a larger number of PrEP users in 2022, with a cost of \$522 million, as shown in **Table 3.5**.

Table 3.5 Estimated PrEP Costs, by Category and Race and Ethnicity: 2022

By Race and Ethnicity*	PrEP Drugs	Ancillary Services	Subtotal: Drugs + Ancillary Services	Outreach and PrEP Navigation	Total
Black	\$1,839,443	\$9,729,134	\$11,568,577	N/A	
Hispanic	\$2,137,655	\$11,380,321	\$13,517,976	N/A	
White	\$3,218,072	\$15,653,076	\$18,871,148	N/A	
Other	\$434,471	\$2,251,427	\$2,685,897	N/A	
All races and ethnicities	\$7,629,641	\$39,013,957	\$46,643,598	\$475,168,750	\$521,812,348

N/A = not applicable; PrEP = pre-exposure prophylaxis.

* Analyses by race and ethnicity move a larger number of people onto PrEP each year to achieve the goals by race and ethnicity of getting half of all eligible people onto PrEP, while not reducing the number on PrEP in the White subpopulation below 2019 levels, which was 78% of the number eligible in the White subpopulation. By 2032, these results assume almost 744,000 people on PrEP versus 671,000 in the scenario that does not aim to achieve goals by race and ethnicity.

The total PrEP cost for this scenario was \$6.22 billion over a 10-year period (**Table 3.6**). These costs are higher than estimated costs shown in **Table 3.4** because our analyses by race and ethnicity move a larger number of people onto PrEP each year to achieve the EHE goals for each race and ethnicity.

Table 3.6 Cumulative Estimated PrEP Costs, by Category and Race and Ethnicity over 10 Years

By Race and Ethnicity*	PrEP Drugs	Ancillary Services	Subtotal: Drugs + Ancillary Services	Outreach and PrEP Navigation	Total
Black	\$147,898,819	\$337,287,892	\$485,186,710	N/A	
Hispanic	\$169,004,498	\$388,242,029	\$557,246,527	N/A	
White	\$97,567,666	\$228,664,080	\$326,231,745	N/A	
Other	\$30,301,562	\$69,080,321	\$99,381,883	N/A	
All races and ethnicities	\$444,772,545	\$1,023,274,321	\$1,468,046,866	\$4,751,687,500	\$6,219,734,366

N/A = not applicable; PrEP = pre-exposure prophylaxis.

* Analyses by race and ethnicity move a larger number of people onto PrEP each year to achieve the goals by race and ethnicity of getting half of all eligible people onto PrEP, while not reducing the number on PrEP in the White subpopulation below 2019 levels, which was 78% of the number eligible in the White subpopulation. By 2032, these results assume 744,000 people on PrEP versus 671,000 in the scenario that does not aim to achieve goals by race and ethnicity.

3.2 HIV Infections Avoided

We estimate that expanding PrEP could result in 74,540 person-years of HIV infections avoided over 10 years. The largest share of these person-years would be for MSM, at approximately 72%. Assuming annual HIV treatment costs of \$28,950 per person per year in 2019 dollars, or \$30,510 in 2021 dollars⁴ (Bingham et al., 2021), results suggests medical cost savings from avoided HIV treatment of more than \$2.27 billion over 10 years.

Table 3.7 Estimated Person-Years of HIV Infections Averted over a 10-Year Period

	Men Who Have Sex with Men	Heterosexuals	People Who Inject Drugs	All Risk Transmission Groups
Estimated person-years of HIV infections averted	53,513	14,692	6,335	74,540

⁴ Per person per year costs are estimated as undiscounted lifetime costs divided by overall additional life expectancy from Bingham and colleagues (2021; Table 3).

3.3 Interviews with Health Centers, Clinics, and a Jurisdiction

We interviewed representatives from two health centers, three clinics, and a jurisdiction across the United States on their approaches to cover costs for PrEP services and any efforts they have implemented to expand PrEP outreach and navigation services and to pay for those services. Because published information on how entities are implementing PrEP programs is limited, we used the information obtained from interviews to inform our analytic assumptions around how entities are using current funding sources to provide needed PrEP services in their population and to gain an understanding of the funding gaps that remain. Our analysis assumes these funding gaps will need to be filled to further expand PrEP coverage and especially to reach subpopulations in which current uptake is low.

The interviews took place over video calls in July and August 2022 and were up to 1 hour long. One clinic sent written responses to our questions in lieu of a meeting. At the start of the interviews, we informed participants that their names and organizations would not be identified in our report.

We asked participants the following questions:

1. Do you use Ready, Set, PrEP? Why or why not? What percentage of your uninsured, PrEP-eligible patients use Ready, Set, PrEP?
2. Do you use Gilead's Advancing Access Program or other Patient Assistance Programs for the uninsured? Why or why not? What percentage of your uninsured PrEP-eligible patients use this program?
3. What percentage of your PrEP-eligible patients are privately insured, uninsured, or have other insurance (e.g., Medicaid, Medicare)?
4. How do you pay for PrEP drug for uninsured PrEP patients?
5. How do you pay for PrEP ancillary services for uninsured PrEP patients?
6. What is the role of 340B revenue in supporting your PrEP services? How do you expect this to change over time over the next 3–5 years?
7. How much do you spend on PrEP drugs for the uninsured? What percentage of the total cost of your spend on all PrEP prescriptions and services is constituted by PrEP drug cost?
8. How do you pay for outreach? How much do you pay for these activities? Have you received PrEP-specific funding from the Bureau of Primary Health Care? How were these funds spent and do you want to share any results?

9. Do you hire PrEP navigation staff? If so, how many full-time equivalents (FTEs)? How many PrEP patients can be supported by a 1.0 FTE PrEP navigator? How do you expect your staff needs will change over the next 3–5 years?
10. What is your split between branded oral PrEP and generic oral PrEP? How do you anticipate this split will change over the next 5–10 years?
11. Are you already prescribing long-acting PrEP? How do you expect that to change over the next 10 years?

Table 3.8 summarizes findings from our interviews.

Table 3.8. Summary of Key Takeaways from Interviews with Health Centers, Clinics, and Jurisdiction

PrEP-Eligible Patient Population	PrEP Drugs	PrEP Ancillary Services	PrEP Outreach to Providers and Community, Patient Navigation, Retention-in-Care
<ul style="list-style-type: none"> ▪ Health centers and clinics in Medicaid expansion states usually had a smaller proportion of uninsured patients than clinics in non-Medicaid expansion states ▪ Clinics may purchase Affordable Care Act health insurance plans for uninsured patients ▪ Stigma may prevent patients from using PrEP and some insured pay for PrEP out-of-pocket due to privacy concerns ▪ Cultural and linguistic barriers may limit PrEP access 	<ul style="list-style-type: none"> ▪ Health centers and clinics primarily prescribe generic and branded oral PrEP, though the share between generic and branded drug varied considerably ▪ The interviewed health centers and clinics do not prescribe long-acting PrEP because it may not be covered by insurance ▪ Eligible health centers, clinics, and jurisdictions rely to some degree on 340B revenue to purchase PrEP drugs ▪ Many health centers and clinics do not routinely enroll clients in Ready, Set, PrEP or manufacturer drug assistance programs because they do not receive funding for the resource and staff time required ▪ Some health centers and clinics utilize state drug assistance programs to pay for PrEP drugs for uninsured patients 	<ul style="list-style-type: none"> ▪ Most state PrEP drug assistance programs cover ancillary services for uninsured patients ▪ Health centers and clinics tended to rely on 340B revenue to provide ancillary services or insurance plans that cover these services to uninsured patients ▪ Clinics that are not federally qualified health centers have fewer existing funding options ▪ Health centers and clinics differ in how much they are impacted by reduced 340B revenue ▪ Health centers and clinics are resourceful with combining existing funding sources to provide ancillary services to uninsured patients ▪ One jurisdiction described a safety net telehealth program to provide ancillary services at no cost to uninsured patients 	<ul style="list-style-type: none"> ▪ Health centers, clinics, and jurisdictions pay for outreach, patient navigation, and adherence services using grants from Health Resources & Services Administration, Centers for Disease Control and Prevention, states, and cities ▪ One jurisdiction described the state health department’s centralized navigation services for PrEP ▪ One health center noted that outreach efforts need to be actionable and sustainable ▪ Health centers and clinics emphasized the importance of funding to invest in hiring and training staff ▪ One clinic uses a mobile van for outreach to PrEP-eligible people

PrEP = pre-exposure prophylaxis.

We used the interview responses to inform our assumptions around costs, beyond those covered through existing federal and state awards and programs, that would be incurred to support expansion of PrEP. Although the health centers, clinics, and jurisdiction reported varied approaches for covering PrEP drugs and ancillary services and for reaching and providing navigation and adherence services, we identified a few key messages that guided our assumptions related to costs, which are summarized in Section 2.1.

First, most entities are finding ways to help clients get enrolled in programs that cover PrEP drug costs or provide copay assistance for out-of-pocket costs related to PrEP. Second, 340B is an important source of revenue that covered entities may use to cover ancillary services costs for clients who lack insurance or who have insurance policies that do not pay for PrEP ancillary services. In some cases, 340B revenue is used to purchase ACA insurance policies that cover PrEP drugs and ancillary services for clients who lack insurance. Third, many barriers remain to increasing rates of PrEP coverage, including stigma, cultural and linguistic barriers, and lack of knowledge in the community and among providers about who qualifies for PrEP, its potential benefits, and the many programs available to support clients in accessing free or low-cost PrEP drugs and ancillary services.

Entities described using awards from CDC, HRSA, states, and cities to fund their current outreach and navigation services for PrEP (NASTAD, 2022). Yet, most expressed a need for additional resources to hire and train staff to provide outreach, PrEP navigation, and PrEP adherence support services to people in the community who are eligible for PrEP but not using it or not adhering to recommendations for use. This investment needs to be large enough to allow entities to expand services, such as providing mobile services, telehealth, and offering injectable long-acting medications to people who are eligible for PrEP. Respondents also noted that this type of outreach and expanded navigation services needs to be sustained to ensure that sufficient numbers of staff are employed to reach EHE goals for PrEP and to facilitate seamless care for individuals, ranging from providing prevention services for HIV, STDs, and family planning to offering diagnosis and treatment services for HIV and other STDs. Building and maintaining these connections between entities that serve people with indications for PrEP are needed to achieve EHE goals.

4. Conclusions

We calculated the costs of expanding PrEP access to achieve the EHE PrEP goals of getting half of individuals eligible for PrEP into PrEP care in 5 years and maintaining the care levels through 10 years. Our main findings are as follows:

- To achieve the goal of moving half of eligible individuals into PrEP care within 5 years, estimated costs would be \$521.1 million in 2022 and \$6.18 billion over a 10-year period.
- Reducing racial and ethnic disparities in the percentage of eligible people who are using PrEP to achieve EHE goals by race and ethnicity will require rapid increases in PrEP use among Black, Hispanic, and other race subpopulations.
- The cost of achieving racial- and ethnic-focused EHE goals would be somewhat higher than the cost of achieving EHE goals without addressing disparities, with a cost of approximately \$6.22 billion over 10 years.

4.1 Study Limitations

This study had several limitations. First, because the PrEP surveillance data do not report the number of people eligible for PrEP or who are using PrEP by insurance status or transmission group, we allocated the eligible population and the numbers using PrEP across four insurance categories using data from multiple sources.

Second, identifying cost inputs for PrEP outreach was challenging. Where data on costs for PrEP programs were unavailable, we initially considered using costs from similar programs for people with HIV but ultimately made assumptions that were consistent with what we heard from interviews with health entities that provide PrEP. Specifically, those entities can often help clients find support for paying for PrEP drugs and ancillary services, but they need additional support to provide outreach and navigation for PrEP to eligible subpopulations.

Related to this issue, we found limited data on the number of people who benefited from drugs and services provided through the 340B program and on the 340B prices paid for specific prescription medications. At a national level, we were unable to identify data on how many clinics or patients use drugs purchased through the 340B program. We also had limited information on expected pricing of oral and long-acting PrEP medications under the 340B program. As a result, our analyses made several assumptions about which brands and formulations PrEP-eligible populations will use over the next 10 years and the 340B prices of those medications.

However, because PrEP_CC is a flexible tool, it is possible to adjust input values and assumptions to explore other plausible scenarios for achieving the EHE PrEP goals.

4.2 Comparison with Other PrEP Assistance Needs Analyses

We compared our inputs and cost estimates for implementing a PrEP Assistance Program with inputs and estimates from two recent proposals for a national PrEP program and to inputs and assumptions from a recent analysis of the financial needs for PrEP. First, HHS released a legislative proposal for fiscal year 2023, which includes a program plan and a budget summary (HHS, 2022a). Second, Killelea and colleagues (2022a, 2022b) proposed an approach for financing a national PrEP program and provided a breakdown of estimated costs. Both proposals emphasize a shift to newly available generic oral PrEP instead of a combination of generic and brand-name PrEP.

The HHS proposal assumes uninsured individuals and people on Medicaid will have PrEP drug costs, whereas our analysis assumes that only 5% of the uninsured would have these costs because of the availability of 340B drug purchases and other programs that provide free PrEP drugs. Our average annual cost estimate is higher than the HHS proposal estimate of **\$237 million** in fiscal year 2023, but our 10-year estimate of \$6.18 billion (in 2021\$) is considerably lower than the HHS estimate of \$9.84 billion.

When comparing our analysis with the Killelea and colleagues (2022a) proposal, there are many similarities. For example, both analyses assume there will be limited direct costs for PrEP drugs or ancillary services for insured individuals because these services are covered by insurance under ACA. However, our estimates of the insurance coverage mix among the PrEP-eligible population over time is more detailed and evidence-based than the Killelea and colleagues (2022a) estimates. Killelea and colleagues (2022a) assumed that roughly half of the PrEP-eligible population is privately insured and that one-half of the remaining population is uninsured or on Medicaid, and thus will require costs for PrEP drugs, visits, and ancillary services. Killelea and colleagues (2022a) also relied on low assumptions for the cost of PrEP drugs and visits and services that would be negotiated by the federal government: a price level of \$600 per year for each of the following: (a) generic FTC/TDF, (b) PrEP laboratory services, and (c) PrEP telehealth visits. Given these assumptions, Killelea and colleagues (2022a) reports an estimated annual cost of **\$250 million** to provide PrEP to half of the people who are uninsured or on Medicaid. However, we find an average annual cost of approximately **\$618 million**, which incorporates evidence from the literature on the insurance mix of individuals who are eligible for PrEP, accounts for expected growth in the number of people using PrEP and allows for substantial investments in outreach and PrEP navigation services to be provided by community health centers, cities, states, health clinics (e.g., STI, family planning, Indian Health Service), and CBOs in order to increase PrEP uptake and eliminate racial and ethnic disparities.

Finally, we considered how our analysis and results compare with those from a presentation at the 2022 International AIDS Conference (Bonacci et al., 2022). Bonacci and colleagues (2022) estimated unmet financial needs for PrEP in the United States in 2018 and found

that fewer than 1% of individuals eligible for PrEP are likely to require assistance for PrEP medications and ancillary services, while an additional 3.9% of eligible individuals will need support for ancillary services. The authors estimated it would cost \$106 million (2018\$) per year to meet these financial needs. Our data inputs and assumptions about financial needs are similar. Among all individuals who are eligible for PrEP, we determined that approximately 20% are uninsured (vs. 15% in Bonacci et al., 2022). We further assumed that 5% of the uninsured will require financial assistance to pay for PrEP medications and ancillary services, and an additional 45% will require financial assistance for ancillary services only. In other words, among the full population eligible for PrEP, our analysis assumed that 1% will require financial assistance for medications and ancillary services and that an additional 9% will require assistance for ancillary services only. We used the Bonacci and colleagues (2022) 340B oral PrEP price of \$5,324 per person per year in our analysis, inflated to \$5,770 in 2021 dollars. However, our analysis also accounted for expected growth in the use of more expensive, long-acting PrEP over time (\$22,200 per person per year, or approximately \$17,000 per year at 340B prices). Our ancillary cost estimate of \$1,977 (2021\$) per year is virtually identical to the overall weighted average cost of \$1,937 per year from Bonacci and colleagues (2022; adjusted to 2021\$ from \$1,788 in 2018\$).

4.3 Conclusion

Our analyses suggest that a national PrEP Assistance Program that provides financial assistance for PrEP medications and ancillary services for those who need it and that makes a substantial investment in expanding outreach and PrEP navigation and adherence services through a broad network of state and local providers and CBOs would cost about \$521.1 million in its first year of operation and \$6.18 billion to \$6.22 billion over a 10-year period. PrEP_CC is a flexible tool that will allow the HIV+Hepatitis Policy Institute to examine other plausible scenarios for achieving EHE PrEP goals and exploring how these scenarios would affect the estimated cost of achieving the EHE PrEP goals through a national PrEP Assistance Program.

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