# Abbreviated Analysis

# California Assembly Bill 554: Antiretroviral Drugs, Drug Devices, and Drug Products

Report to the 2025–2026 California State Legislature

APRIL 22, 2025

California Health Benefits Review Program (CHBRP), University of California, Berkeley

# Abbreviated Analysis of California Assembly Bill 554: Antiretroviral Drugs, Drug Devices, and Drug Products

Summary to the 2025-2026 California State Legislature, April 22, 2025



#### **Summary**

The version of California Assembly Bill (AB) 554 analyzed by California Health Benefits Review Program (CHBRP) would, in Year 1, require largegroup health plans regulated by the Department of Managed Health Care (DMHC) and large-group policies regulated by the California Department of insurance (CDI) to cover U.S. Food and Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)recommended antiretroviral (ARV) drugs, devices, and products for the prevention of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), with no cost sharing, prior authorization, step therapy, or utilization review requirements. DMHC- and CDI-regulated smallgroup and individual health plans and policies would be required to abide by the same requirements in Year 2 postmandate.

In 2026, of the 22.2 million Californians enrolled in state-regulated health insurance, 9.2 million would have insurance subject to AB 554 in Year 1. In Year 2 this total would increase to 13.6 million enrollees.

#### **Benefit Coverage**

At baseline, CHBRP estimates approximately 95.5% of health plans and policies are fully compliant with AB 554. Postmandate, 100% of health plans and policies regulated by DMHC and CDI would be fully compliant. AB 554 would not exceed essential health benefits (EHBs).

#### Cost Impacts<sup>1</sup>

In Year 1 (2026), AB 554 would result in an additional 1,566 enrollees newly utilizing ARV drugs, and a total of 25,079 additional enrollees using ARV drugs without cost sharing. This would result in an additional \$30.5 million in annual expenditures, including a \$73.6 million increase

<sup>1</sup> Similar cost and health impacts could be expected for the following year though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

in total premiums, and a decrease of \$43 million in enrollee cost sharing.

In Year 2, CHBRP estimates AB 554 would result in a net annual expenditure of \$37,087,000 (0.02%), including an increase in total premiums paid by employers and enrollees for newly covered benefits by \$135,988,000, and a decrease in enrollee cost sharing by \$98,901,000 (0.48%) compared to baseline.

CHBRP was unable to estimate additional cost offsets related to the number of HIV infections prevented due to increased use of ARV drugs. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to estimated premium increases.

#### Context

HIV attacks the body's CD4 and/or T-cells (i.e., a type of white blood cell), which are integral to the body's immune function. If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection;<sup>2</sup> (2) chronic HIV infection; and (3) AIDS. There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through ARV therapy.

ARV therapy is the use of HIV medicines — also referred to as an HIV regimen — to treat or prevent HIV. There are more than 30 FDA-approved ARV drugs from eight drug classes that may be used to:

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<sup>&</sup>lt;sup>2</sup> Refer to CHBRP's full report for full citations and references.



- Prevent initial HIV infection (i.e., preexposure prophylaxis [PrEP] or postexposure prophylaxis [PEP]); or
- Treat HIV infection, prevent HIV transmission to other people, and prevent progression to AIDS.

Given the availability of ARV drugs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

#### **Bill Summary**

AB 554 would require DMHC-regulated plans and CDI-regulated policies to cover FDA-approved or CDC-recommended ARV drugs, devices, and products for the prevention of HIV/AIDS, with no cost sharing or utilization review requirements. In addition, the bill language specifies that ARV drugs, devices, or products must not be subject to prior authorization, step therapy, or any other protocol designed to delay treatment. Coverage for all therapeutically equivalent versions of ARV drugs without prior authorization or step therapy would not be required if at least one therapeutic equivalent version is covered without prior authorization, step therapy requirements, or cost sharing, pursuant to an exception request.

AB 554 would apply to grandfathered and nongrandfathered DMHC-regulated health plans and CDI-regulated policies in the large-group market in Year 1. In Year 2, the bill would extend to include small-group and individual market insurance. DMHC-regulated Medi-Cal plans are excluded. Figure A notes how many Californians have health insurance that would be subject to AB 554.

#### **Impacts**

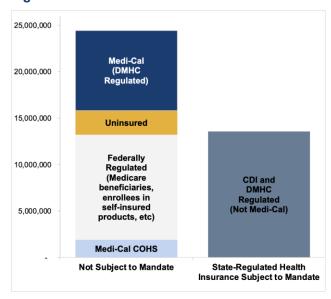
#### **Benefit Coverage**

CHBRP estimates that at baseline, 8,794,000 (95.5%) Californians with state-regulated insurance subject to the mandate are enrolled in plans or policies that are fully compliant with AB 554 and have coverage for ARV drugs without cost sharing. Approximately 2.1% of health plans and policies are in partial compliance (i.e., provide coverage but with cost sharing), and 2.4% are out of compliance (i.e., do not provide coverage). Postmandate, 100% of enrollees with health insurance subject to AB 554 would have coverage for ARV drugs without cost sharing.

#### Utilization

At baseline, CHBRP estimates 63,155 enrollees utilize ARV drugs each year, about half (53.5%) of whom also have cost sharing.

Figure A. Health Insurance in CA and AB 554



Source: California Health Benefits Review Program, 2025.
Key: CDI = California Department of Insurance; COHS = County
Organized Health System; DMHC = Department of Managed Health
Care

CHBRP assumed that in Year 1 postmandate, there would be an increase in utilization, driven primarily by new benefit coverage in grandfathered large-group plans. CHBRP estimates an additional 25,079 enrollees would utilize ARV drugs without cost sharing in Year 1.

In Year 2 postmandate, when the mandate would apply to small-group and individual health plans and policies, in addition to the assumptions made for Year 1 utilization. CHBRP assumed further increases in utilization due to a new ARV drug. The FDA is expected to approve a long-acting injectable (lenacapavir) that requires two doses a year for use as PrEP in 2025. Based on historical data on the introduction of other long-acting injectable drugs to the market, CHBRP estimates that lenacapavir will not be readily available until 2027. CHBRP anticipates that uptake of lenacapavir will increase overall utilization of ARV drugs in Year 2 because of interest in a PrEP regimen that requires less frequent doses to maintain. Based on these assumptions, CHBRP estimates an additional 37,043 enrollees would utilize ARV drugs without cost sharing compared to baseline in Year 2.



Following Year 2, utilization may be similar to that of other long-acting injectables during the first years they were available on the market.

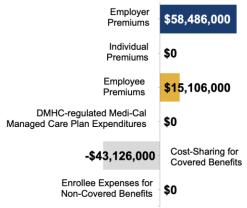
#### **Expenditures**

In the first year postmandate, AB 554 would result in an additional \$30.5 million (0.02%) in net annual expenditures, including a \$73.6 million increase in total premiums, and a decrease of \$43 million (0.23%) in enrollee cost sharing for enrollees in large-group DMHC-regulated plans and CDI-regulated policies.

In Year 2, CHBRP estimates AB 554 would result in a net annual expenditure of \$37,087,000 (0.02%), including an increase in total premiums paid by employers and enrollees for newly covered benefits by \$135,988,000, and a decrease in enrollee cost sharing by \$98,901,000 (0.48%) compared to baseline.

CHBRP was unable to estimate additional cost offsets related to the number of HIV infections prevented due to increased use of ARV drugs. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to AB 554.

Figure B. Expenditure Impacts of AB 554 (Year 1)



**Source: California Health Benefits Review Program, 2025.** Key: DMHC = Department of Managed Health Care.

#### Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be no impact because these plans are excluded from the bill mandate.

#### **CalPERS**

For enrollees associated with the California Public Employees' Retirement System (CalPERS) in DMHC-regulated plans, CHBRP estimates premiums would increase by \$0.64 per member per month (PMPM) for a total of approximately \$5.9 million (0.08%) in Year 1 compared to baseline.

In Year 2, premiums would increase by \$6,181,000 (0.07%) for enrollees associated with CalPERS in DMHC-regulated plans compared to baseline.

#### Covered California - Individually Purchased

In Year 1, AB 554 would not apply to any health plans or policies in the individual market.

In Year 2, premiums would increase by approximately \$21.3 million (0.12%) for Covered California individual market plan enrollees, and mirror plans available to individuals outside of Covered California would see an increase in premiums of about \$10.6 million (0.16%).

#### Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 554.

#### **Long-Term Impacts**

Cost impacts over the long term would be proportional to any increase in utilization. New ARV drugs, devices, and products that may be developed in the future could have additional impacts on utilization in the long-term. However, cost is not the only barrier to access to ARV therapy. Provider awareness, stigma, inequities in healthcare access, low perception of risk, and other factors also create challenges that impact ARV drug utilization and adherence, and ultimately the incidence and prevalence of HIV/AIDS.

## **Essential Health Benefits and the Affordable Care Act**

Because ARV drugs are already covered under the EHB benchmark plan, AB 554 would not exceed the definition of EHBs in California.



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#### **Acronyms and Abbreviations**

AB - Assembly Bill

ACA - Affordable Care Act

AIDS - acquired immunodeficiency syndrome

ARV - antiretroviral

CA - California

CalPERS - California Public Employees' Retirement System

CDC - Centers for Disease Control and Prevention

CDI - California Department of Insurance

CHBRP - California Health Benefits Review Program

CHSD - Milliman's Consolidated Health Cost Guidelines Sources Database

COHS - County Organized Health System

DHCS - Department of Health Care Services

DMHC - Department of Managed Health Care

EHB - Essential Health Benefits

HDHP - high deductible health plan

HIV - human immunodeficiency virus

HMO - Health Maintenance Organization

HSA - health savings account

MSM - men who have sex with men

NDC - National Drug Code

PAGAA - Panel on Antiretroviral Guidelines for Adults and Adolescents

PEP – postexposure prophylaxis

PMPM – per member per month

PrEP – preexposure prophylaxis

SB - Senate Bill

TasP – treatment as prevention

USPHS - U.S. Public Health Service

USPSTF - United States Preventive Services Task Force



State-Regulated Health

Insurance Subject to Mandate

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#### Introduction

The California Assembly Committee on Health requested that the California Health Benefits Review Program (CHBRP)<sup>3</sup> conduct an evidence-based assessment of the financial impacts of Assembly Bill (AB) 554, Antiretroviral Drugs, Drug Devices, and Drug Products.

# Bill Language for AB 554, Antiretroviral Drugs, Drug Devices, and Drug Products

AB 554 would require coverage of all U.S. Food and Drug Administration (FDA)—approved or Centers for Disease Control and Prevention (CDC)—recommended antiretroviral (ARV) drugs, devices, and products for the prevention of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), with no cost sharing or utilization review requirements. In addition, the bill language specifies that ARV drugs, devices, and products must not be subject to prior authorization, step therapy, or any other protocol designed to delay treatment. Coverage for all therapeutically equivalent versions of ARV drugs without prior authorization or step therapy (i.e., utilization management techniques) would not be required if at least one therapeutic equivalent ARV drug is covered without prior authorization, step therapy requirements, or cost sharing, pursuant to an exception request.

See the full text of AB 554 in Appendix A.

25,000,000 
Medi-Cal
(DMHC
Regulated)

15,000,000 
Uninsured

Federally
Regulated
(Medicare
beneficiaries,
enrollees in
self-insured
(Not Medi-Cal)

Figure 1. Health Insurance in CA and AB 554

Source: California Health Benefits Review Program, 2025. Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

products, etc)

Medi-Cal COHS

Not Subject to Mandate

If enacted, AB 554 would apply to the health insurance of approximately 9.2 million enrollees (24.2% of all Californians) in Year 1 (2026), and approximately 13.6 million enrollees (35.7% of all Californians) in Year 2 (2027) (see Figure 1).

#### Includes:

- In Year 1 (2026), enrollees with large-group commercial or California Public Employees' Retirement System (CalPERS) health insurance in grandfathered and nongrandfathered plans regulated by DMHC and policies regulated by CDI.
- In Year 2 (2027), enrollees with all commercial or CalPERS health insurance in grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies (i.e., those in the large-group, small-group, and individual markets).
- **Excludes:** Medi-Cal beneficiaries enrolled in DMHC-regulated plans or county organized health system (COHS) plans.

See the following Analytic Approach and Key Assumptions section for additional information.

Appendix B provides an overview of the cost-sharing and utilization management practices that are addressed by AB 554.

<sup>&</sup>lt;sup>3</sup> See CHBRP's authorizing statute.



#### What Is HIV/AIDS? What Are Antiretrovirals?

HIV attacks the body's CD4 and/or T-cells (i.e., a type of white blood cell), which are integral to the body's immune function. If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection;<sup>4</sup> (2) chronic HIV infection;<sup>5</sup> and (3) AIDS<sup>6</sup> (CDC, 2022a). There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through the use of ARV therapy (CDC, 2023). ARV therapy is the use of a combination of HIV medicines — also referred to as an HIV regimen — to treat or prevent HIV.

There are more than 30 FDA-approved ARV drugs from eight drug classes that may be used to:

- Prevent initial HIV infection (i.e., preexposure prophylaxis [PrEP] or postexposure prophylaxis [PEP]); or
- Treat HIV infection, prevent HIV transmission to other people, and prevent progression to AIDS (HHS, 2025).

Given the availability of ARV drugs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population (Antiretroviral Therapy Cohort Collaboration, 2017).

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<sup>&</sup>lt;sup>4</sup> Acute HIV infection occurs within the first 2 to 4 weeks of exposure, in which many individuals may present with flu-like symptoms (e.g., fever, fatigue, and/or swollen lymph nodes). During this stage, HIV is highly contagious (CDC, 2022a).

<sup>&</sup>lt;sup>5</sup> Chronic HIV infection (i.e., asymptomatic HIV infection or clinical latency) can last between 10 and 15 years if left untreated. HIV is still active but individuals may not present with any symptoms and may continue to be contagious (CDC, 2022a).

<sup>&</sup>lt;sup>6</sup> During AIDS, the body's immune system is severely compromised with a CD4 count below 200 cells per cubic millimeter of blood. A normal CD4 count for an HIV-negative person ranges between 500 to 1500 cells per cubic millimeter (Garcia and Guzman, 2022). During this stage, individuals present with a high viral load and may easily transmit HIV to others (CDC, 2022a).



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#### **Policy Context**

The Assembly Committee on Health has requested that CHBRP<sup>7</sup> conduct an evidence-based assessment of the financial impacts of AB 554, Antiretroviral Drugs, Drug Devices, and Drug Products, as amended on March 3, 2025.

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

#### **California Law and Regulations**

Existing law prohibits step therapy and prior authorization of medically necessary antiretroviral drugs, including PrEP and PEP, for the prevention of AIDS/HIV in nongrandfathered health plans and policies. Coverage is not required for all therapeutically equivalent versions of ARV drugs without prior authorization or step therapy if at least one drug is covered without prior authorization or step therapy. California law also requires coverage of PrEP and PEP that has been furnished by a pharmacist, including the pharmacist's services and related testing ordered by them.<sup>8</sup>

#### **Preventive services**

Existing California law requires coverage, without cost sharing or prior authorization, for preventive services with Grade A and B recommendations from the United States Preventive Services Task Force (USPSTF), for enrollees in grandfathered and nongrandfathered plans and policies. <sup>9,10</sup> This requirement mostly aligns with the federal preventive services listed under the Affordable Care Act, which only applies to nongrandfathered plans and policies. <sup>11</sup> USPSTF currently has a Grade A recommendation for the prescription of PrEP with effective antiretroviral therapy to decrease the risk of acquiring HIV in adolescents and adults who do not have HIV and are at increased risk of contracting the virus (USPSTF, 2023).

#### **California Patient Assistance Programs**

The California Department of Public Health (CDPH) Office of AIDS administers the PrEP Assistance Program to increase accessibility to, and uptake of, PrEP for eligible Californians. Clients fully enrolled in the program have access to several services at no cost, including:

- ARV drugs (including PrEP and PEP);
- Medications for the treatment and prevention of sexually transmitted infections;
- Testing for HIV, sexually transmitted infections, hepatitis, pregnancy, and PrEP initiation; and
- PrEP-related office visits and services.

Criteria for full enrollment requires proof of Identification and California residency, testing negative for HIV, an annual income of less than 500% of the Federal Poverty Level, and ineligibility for full coverage by a third-party insurer. Those who do not meet this criterion due to age, confidentiality concerns, or the need for temporary coverage may still access limited services depending on how many of the first three criteria listed above they meet (CDPH, 2022b).

The CDPH Office of AIDS also administers the AIDS Drug Assistance Program for people diagnosed with HIV or AIDS. The program provides eligible Californians with free FDA-approved medications for the treatment and suppression of HIV/AIDS and HIV/AIDS-related opportunistic infections, and premium pay assistance (CDPH, 2022c). Eligibility criteria

<sup>&</sup>lt;sup>7</sup> CHBRP's authorizing statute is available <u>here</u>.

<sup>&</sup>lt;sup>8</sup> Health and Safety Code (HSC) 1342.74; Insurance Code (INS) 10123.1933.

<sup>9</sup> HSC 1367.002; INS 10112.2.

<sup>&</sup>lt;sup>10</sup> More information about the state and federal requirements to cover specified preventive services is included in CHBRP's <u>resource</u> Federal Recommendations and the California and Federal Preventive Services Benefit Mandates.

<sup>&</sup>lt;sup>11</sup> As of the published date of this report, the federal preventive services mandate was being challenged in court. Due to the alignment between California and federal law regarding coverage, cost sharing, and utilization management of certain preventive services, the court case will not impact DMHC-regulated health plans or CDI-regulated health policies. For more information, see CHBRP's resource Federal Recommendations and the California and Federal Preventative Services Benefit Mandates.



includes being at least 18 years of age and a California resident, having a positive HIV/AIDS diagnosis, an annual Modified Adjusted Gross Income (MAGI) that does not exceed 500% of the Federal Poverty Level based on household size and income, and not being fully covered by Medi-Cal or any other third-party payers.

AB 554 would provide similar access to ARV drugs for enrollees in state-regulated health insurance but would not require the same eligibility requirements as those mandated by the above CDPH programs.

#### **Previous California Legislation**

California previously introduced SB 339 (2023), which authorized a pharmacist to furnish up to a 90-day course of PrEP, or beyond 90-days under specified conditions. It also required DMHC-regulated plans and CDI-regulated policies to include coverage for PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist. SB 339 was chaptered on February 6, 2024.

SB 427 (2023) was nearly identical to AB 554. SB 427 did not include language relating to therapeutic equivalency of long-acting injectable drugs. SB 427 was held in the Assembly.

#### **Similar Legislation in Other States**

Nine states have introduced legislation this year related to coverage of ARV drugs and related terms and conditions (Figure 2). New York, North Dakota, Oregon, and Pennsylvania are considering bills that would prohibit cost sharing or prior authorization on coverage for ARV drugs.12 Illinois, Indiana, Massachusetts, and Minnesota have introduced legislation prohibit cost sharing and/or prior authorization for PrEP or PEP, specifically. 13 Nebraska is deliberating a proposed state mandate to cover PrEP.14



Figure 2. States With Pending Legislation Related to ARV Drugs

Source: California Health Benefits Review Program, 2025; created with mapchart.net.

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<sup>14</sup> Nebraska Legislative Bill 715.

<sup>12</sup> New York S05534 and A00026; North Dakota SB2076; Oregon House Bill (HB) 2292; Pennsylvania HB719.

<sup>&</sup>lt;sup>13</sup> Illinois HB2584 and SB1258; Indiana HB1298; Massachusetts H1245; Minnesota House File 973 and Senate File 1599.



#### **Federal Policy Landscape**

#### **Affordable Care Act**

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 554 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs). 15,16

#### Essential health benefits

In California, nongrandfathered<sup>17</sup> individual and small-group health insurance is generally required to cover essential health benefits (EHBs).<sup>18</sup> In 2026, approximately 11% of all Californians will be enrolled in a plan or policy that must cover EHBs.<sup>19</sup>

States may require state-regulated health insurance to offer benefits that exceed EHBs. <sup>20,21,22</sup> Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs. <sup>23,24</sup> Because ARV drugs are already covered under the EHB benchmark plan, AB 554 would not exceed the definition of EHBs in California. <sup>25</sup>

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<sup>&</sup>lt;sup>15</sup> The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website.

<sup>16</sup> Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

<sup>&</sup>lt;sup>17</sup> A grandfathered health plan is "a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers."

<sup>18</sup> For more detail, see CHBRP's issue brief Essential Health Benefits: An Overview of Benefits, Benchmark Plan Options, and EHBs in California.

<sup>&</sup>lt;sup>19</sup> See CHBRP's resource Sources of Health Insurance in California.

<sup>&</sup>lt;sup>20</sup> ACA Section 1311(d)(3).

<sup>&</sup>lt;sup>21</sup> State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013.

<sup>&</sup>lt;sup>22</sup> However, as laid out in the Final Rule on EHBs U.S. Department of Health and Human Services (HHS) released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those statemandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

<sup>&</sup>lt;sup>23</sup> Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and qualified health plan issuers would be responsible for calculating the cost that must be defrayed. Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013.

<sup>&</sup>lt;sup>24</sup> Both Massachusetts and Utah currently pay defrayment costs for exceeding EHBs. For more information about defrayal, refer to CHBRP's <u>issue brief</u> Essential Health Benefits: Exceeding EHBs and the Defrayal Requirement.

<sup>&</sup>lt;sup>25</sup> California EHB benchmark plan (2025-2027).



#### **Analytic Approach and Key Assumptions**

CHBRP previously analyzed similar bill language, SB 427 in 2023. Where applicable, this analysis builds off that previous analysis.

#### **ARV Drugs, Devices, and Products**

As of the date of publication of this report, there are no FDA-approved or CDC-recommended antiretroviral devices or products; therefore, CHBRP's analysis focuses only on ARV drugs.

#### **ARV Drugs Relevant to AB 554**

AB 554 would mandate coverage of FDA-approved and CDC-recommended ARV drugs, devices, and products for the prevention of HIV/AIDS. CHBRP assumed that all FDA-approved and CDC-recommended ARV drugs would apply to AB 554, including those indicated for treatment of HIV, based on the multipronged strategy endorsed by the CDC to end the HIV epidemic. The approach includes targeting prevention of new HIV transmissions to the HIV-negative population through the use of proven interventions such as PrEP and PEP, in addition to treating the HIV-positive population to prevent the progression of HIV to AIDS, and to prevent transmission of HIV to the HIV-negative population by reducing viral load in those who are HIV-positive. See the *Background on ARV Drugs* section for more information.

#### **New ARV Drugs on the Market**

Since the publication of CHBRP's analysis of SB 427 (2023), one new HIV medication, rilpivirine PED (EDURANT PED), has been approved by the FDA (NIH, 2024). Rilpivirine PED is an ARV drug used in combination with other drugs in pediatric patients. CHBRP does not anticipate the introduction of rilpivirine PED to increase utilization of ARV drugs in the first or second year postmandate, because it is within the same drug class as other ARV drugs currently available.

The FDA is currently investigating the use of lenacapavir (SUNLENCA) as a drug to prevent HIV infection in HIV-negative persons, with an expected decision by June 19, 2025 (Gilead, 2025). Lenacapavir is presently indicated for use, in combination with other ARV drugs, for the treatment of HIV in patients whose current ARV regimen is failing due to resistance, intolerance, or safety considerations (NLM, 2024). Based on the outcomes and strength of studies submitted with the application for FDA approval of lenacapavir, CHBRP assumes that FDA approval will be granted for the drug as PrEP medication this year. However, given the implementation timeline of other long-acting ARV drugs following their FDA approval, CHBRP assumes lenacapavir will not be readily available as a PrEP regimen until the 2027 benefit year and has modeled fiscal impacts with the assumption that lenacapavir would be available in Year 2 postmandate.

If any of the assumptions listed above are incorrect, the impact of the bill would differ from the estimates projected by CHBRP. In particular, if lenacapavir is not approved by the FDA in 2025, the fiscal impact of the bill would be lower.

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<sup>&</sup>lt;sup>26</sup> Communication with content expert, Dr. J. Cocohoba, March 2025.



#### **Background on ARV Drugs**

As noted in the *Policy Context* section, AB 554 would require coverage of all FDA-approved or CDC-recommended ARV drugs, devices, and products for the prevention of HIV/AIDS, with no cost sharing, prior authorization, step therapy, or utilization review requirements, in nongrandfathered and grandfathered state-regulated health plans and policies. Health plans would not need to cover all therapeutically equivalent versions without prior authorization or step therapy (i.e., utilization management techniques) if at least one therapeutic equivalent ARV drug is covered without prior authorization, step therapy requirements, or cost sharing pursuant to an exception request.

This background section provides information related to ARV drugs for the prevention of HIV/AIDS.

#### **Strategies for Prevention of HIV/AIDS**

The U.S. Department of Health and Human Services (HHS) is the coordinator of the *Ending the HIV Epidemic in the US* initiative, which has set a goal of reducing new HIV infections in the United States by 90% by 2030, and advancing health equity by scaling up key HIV prevention and treatment strategies (CDC, 2024a). Two of these strategies include the use of proven interventions such as preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), and the implementation of treatment as prevention (TasP). PrEP and PEP are ARV drugs used by the HIV-negative population to prevent contraction of the virus; PrEP is taken prior to possible HIV exposure to reduce the risk of transmission, whereas PEP is taken after a potential exposure to prevent the risk of transmission. TasP is a prevention strategy that concentrates on the treatment of the HIV-positive population to prevent HIV transmission and the progression of HIV to AIDS.

#### **ARV Drugs for HIV/AIDS Prevention: HIV-Negative Population**

Preventing the transmission of HIV to the HIV-negative population has been the focus of a concerted U.S. public health effort for more than 30 years. The initiative has included several elements, such as education, needle exchanges, condom programs, and, the subject of AB 554, ARV drugs. The ARV drugs used to prevent the contraction of HIV to the HIV-negative population are PrEP and PEP. Both strategies use ARV drugs to abort the establishment of chronic HIV infection. By protecting the cells, these medications eliminate the ability of HIV to replicate and destroy the immune system. The drug compounds used in PrEP and PEP regimens also may be used as part of a larger HIV treatment regimen.

#### **PrEP**

PrEP is a long-term regimen<sup>27</sup> recommended for the population that has repeated, intimate exposure to HIV-positive individuals or other high-risk individuals of unknown HIV status. Per the CDC/U.S. Public Health Service's *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update*, it is recommended that all health care providers perform an HIV risk-behavior assessment using approved questions and baseline HIV test, and prescribe a PrEP regimen for those patients at high risk for HIV (CDC/USPHS, 2021). PrEP is indicated for all routes of sexual exposure (CDC/USPHS, 2021). PrEP can be administered in oral (i.e., pill) or injection form. At present, there are two FDA-approved oral medications for use as PrEP, one FDA-approved injectable medication for use as PrEP, and one injectable medication under FDA review (see Table 1) (CDC, 2022b).

<sup>&</sup>lt;sup>27</sup> For individuals not at ongoing risk for getting HIV, those individuals may opt for on-demand PrEP (also known as intermittent, non-daily, event-drive, or off-label PrEP use). Per the CDC, on-demand PrEP may be taken on a 2-1-1 schedule (i.e., 2 pills 2 to 24 hours prior to sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose) (CDC/USPHS, 2021). Additional intermittent PrEP strategies are currently under investigation.



**Table 1. PrEP Medications** 

Generic Medication	Brand Name	Common Dosage	Frequency	Potential Side Effects
Tenofovir disoproxil fumarate	Truvada	ruvada 200 mg/300 mg O		Rash, headache, nausea, abdominal pain, weight loss, loss of bone mineral density (a)
Emtricitabine and tenofovir alafenamide	Descovy	200 mg/25 mg	Oral tablet, once per day	Diarrhea, nausea, headache, fatigue, stomach discomfort, weight gain, loss of bone mineral density (a)
Cabotegravir (long-acting)	Apretude	600 mg	Intramuscular injection every 2 months (b)	Pain, tenderness, and skin induration at the injection site
Lenacapavir (pending FDA approval)	Sunlenca	Initiation:  a) 2 x 300 mg (oral) and 927 mg (SQ) on day 1, and 2 x 300 mg (oral) on day 2; or  b) 2 x 300 mg (oral) on days 1 and 2, 1 x 300 mg (oral) on day 8, and 927 mg SQ on day 15  Maintenance: 927 mg SQ	Oral tablets and SQ injections, followed by SQ injections every 6 months (c)	Pain, redness, and skin induration at the injection site

Source: California Health Benefits Review Program, 2025; based on CDC/USPHS, 2021, and PAGAA, 2024.

Notes: (a) Rare but serious side effects include kidney and liver problems, and potentially fatal lactic acidosis (i.e., lactic acid build-up in the bloodstream).

- (b) Cabotegravir is administered via injection into the gluteal muscle.
- (c) Lenacapavir is administered via injection into the abdomen.

Key: FDA = U.S. Food and Drug Administration; mg = milligrams; PrEP = pre-exposure prophylaxis; SQ = subcutaneous.

#### PEP

PEP is a short-term, daily therapy similar to PrEP. PEP is considered an emergency treatment and recommended for those with episodic suspected or confirmed exposure such as sexual assault survivors, workers with occupational exposure (e.g., prison or health care systems after a needlestick injury), men who have sex with men (MSM), people who inject drugs, as well as for the prevention of perinatal HIV transmission in infants.<sup>28</sup> Per the CDC's *Updated Guide for Antiretroviral Postexposure Prophylaxis*, this regimen must be started within 72 hours of (suspected) HIV exposure and is only taken for 28 days (CDC/HHS, 2016). In combination with the fixed dose combination tablet tenofovir disoproxil fumarate/emtricitabine, adult patients also take another drug such as raltegravir (twice) or dolutegravir (once) daily.

#### ARV Drugs for HIV/AIDS Prevention: HIV-Positive Population

Sustained HIV treatment reduces a person's viral load, or the amount of HIV in their blood. It is possible for HIV treatment to make the viral load so low that it is undetectable. People with an undetectable viral load will not transmit HIV to others through sex. Furthermore, undetectable viral loads reduce the risk of HIV transmission through sharing drug injection equipment, and during pregnancy, labor, and delivery (CDC, 2025). This is the foundation for the Treatment as Prevention strategy, also known as the "Undetectable = Untransmittable" strategy, for HIV prevention (CDC, 2021; CDC, 2024b; HHS, 2023). CDC is a leader of the global movement to promote Undetectable = Untransmittable, and Treatment as

<sup>&</sup>lt;sup>28</sup> It's important to note that the prevention of perinatal HIV transmission is composed of three components: (1) fully suppressive ARV drugs among pregnant persons throughout pregnancy; (2) intrapartum ARV drugs (intravenous zidovudine [ZDV] prophylaxis) among pregnant persons near the time of delivery; and (3) a postexposure prophylaxis to prevent transmission from mother to newborn baby (NIH, 2023).



Prevention (CDC, 2024). Treatment of HIV reduces the progression of the virus to AIDS, thus reducing the mortality and morbidity of AIDS. In 2022, the crude death rate of Californians diagnosed with HIV was 5.4 per 100,000, which is a 17.% increase since 2018 (CDPH, 2024a).

HIV treatment involves the utilization of highly effective ARV drugs<sup>29</sup> to suppress HIV replication.<sup>30</sup> Per the Panel on Antiretroviral Guidelines for Adults and Adolescents (PAGAA), ARV drugs are recommended for all individuals with HIV, regardless of CD4 cell count, to reduce HIV-related morbidity and mortality during all stages of infection (HHS, 2024b). The goal of ARV drugs is to provide a strong yet safe and tolerable (and easy-to-adhere-to) regimen for those with HIV to achieve sustained viral suppression. For most people, current treatment guidelines recommending initiation of an HIV treatment regimen depends on their history of using cabotegravir as PrEP.

In general, PAGAA recommends an initial HIV treatment regimen to include a combination of three or more ARV drugs from at least two different HIV drug classes. For those patients who have previously taken other ARV drugs, are living with a strain of HIV that is resistant to ARV drugs, and whose current ARV regimen is failing, physicians may prescribe a capsid inhibitor. Within the HIV virus, a protein shell, known as a capsid, surrounds and protects the genetic material and enzymes needed for the replication of the virus. Capsid inhibitors are a class of drugs that interfere with the capsid during different stages of the viral life cycle (HIV.gov, n.d.).

Lenacapavir (SUNLENCA) is a capsid inhibitor currently indicated for HIV treatment in heavily treatment—experienced<sup>31</sup> adults with multidrug resistant HIV whose current ARV regimen is failing due to resistance, intolerance, or safety considerations. It is a long-acting injectable delivered subcutaneously and must be used in combination with other ARV drugs. Initiation of the treatment regimen begins one of two ways, based on the recommendation of a health care provider. One initiation option is to take 600 mg orally in addition to 927 mg subcutaneously on day 1, and another 600 mg orally on day 2. The other option is to take 600 mg orally on days 1 and 2, 300 mg orally on day 8, and receive 927 mg via subcutaneous injection on day 15. Maintenance for either option involves a subcutaneous delivery of 927 mg of lenacapavir 6 months following initiation, and then every 6 months afterwards (PAGAA, 2024). As mentioned in the previous section, lenacapavir is currently under FDA review for use as PrEP, in addition to its current use as HIV treatment. If approved, it would be the only PrEP medication that requires two doses per year.

Additional details regarding recommended initial ARV regimens can be found in the PAGAA guidelines (PAGAA, 2024).

#### HIV Prevalence and Incidence in California

Ongoing California Department of Public Health (CDPH) HIV surveillance over the years indicates promising progress in the reduction of new HIV infections as part of a broader nationwide initiative launched by the U.S. Department of Health and Human Services in 2019 (i.e., the Ending the HIV Epidemic in the US initiative). From 2018 to 2022, the number of new HIV diagnoses remained relatively steady in California. New diagnoses increased by 0.4%, from 4,863 in 2018 to 4,882 in 2022 (CDPH, 2024a), while the rate of new diagnoses per 100,000 population declined by approximately 0.8%, from 12.3 to 12.2 (CDPH, 2024a). During the same 4-year period (2018 to 2022), the number of persons living with HIV increased in California — from approximately 136,100 to more than 142,700 — indicating the effectiveness of initiating and sustaining ARV use (CDPH, 2024a).

Table 2 identifies prevalence and incidence of HIV in California by select demographic characteristics (i.e., age, race/ethnicity, and gender) in 2022.

<sup>&</sup>lt;sup>29</sup> Bill language refers to any FDA-approved (or CDC-recommended) ARV drugs, devices, or products. To date, CHBRP is unaware of any FDA-approved or CDCrecommended ARV products or devices.

<sup>&</sup>lt;sup>30</sup> There are more than 50 antiretroviral drugs from eight FDA-approved HIV drug classes (HHS, 2024a). To view a complete list of the eight FDA-approved HIV drug classes, refer to Appendix C.

<sup>&</sup>lt;sup>31</sup> A person with HIV is considered treatment-experienced if they currently take or have previously taken ARV drugs.



Table 2. Prevalence and Incidence of HIV by Select Demographic Characteristics in California, 2022

Demographic Characteristic	Prevalence N (Rate)	Incidence N (Rate)
Age, years		
18-24	2,516 (97.1)	723 (29.4)
25-34	19,619 (757.7)	1,852 (70.7)
35-44	27,426 (1,045)	1,178 (44.9)
45-54	31,094 (1,237.4)	589 (23.6)
55 and older	61,923 (2,235)	497 (18.8)
Race/ethnicity		
American Indian/Alaska Native	309 (176.3)	21 (12.0)
Asian	6,291 (120.1)	249 (4.8)
Black/African American	23,393 (1,012.3)	717 (31.0)
Latino	58,067 (364.8)	2,767 (17.4)
Multiple races/unknown races	4,780 (510.4)	98 (8.7)
Native Hawaiian/other Pacific Islander	272 (188.4)	17 (11.8)
White	48,656 (319.5)	1,013 (6.7)
Gender		
Alternative gender identity	24 (–)*	11 (–)*
Cisgender men	123,109 (614.3)	4,075 (20.3)
Cisgender women	16,864 (83.9)	637 (3.2)
Transgender men	90 (–)*	3 (–)*
Transgender women	2,685 (–)*	156 (–)*
Total	142,772 (355.6)	4,882 (12.2)

Source: California Health Benefits Review Program, 2025, adapted from CDPH, 2024a. Note: Rates are per 100,000 population.

\*Dash (–) indicates rates not calculated due to unknown population denominators. Key: N = total number.



#### Disparities<sup>32</sup> in ARV Drug Uptake, Adherence, and Viral Suppression

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature.

CHBRP found literature identifying disparities in ARV drug uptake, adherence, and viral suppression by race/ethnicity, gender identity/sexual orientation, and age.

#### **Race or Ethnicity**

Black people in California are disproportionately affected by new HIV diagnoses with rates 4.4 times higher among men and nearly 5.7 times higher among women than for White people (CDPH, 2024b). Similarly, Latino people in California are disproportionately affected by new HIV diagnoses with rates 2.7 times higher among men and 1.7 times higher among women than for White people (CDPH, 2024b). CHBRP found several studies indicating racial/ethnic disparities in ARV use and viral suppression among Black people in California (CHRP, 2014; Landovitz et al., 2017). The California HIV/AIDS Research Program found that 34% of Black people who were diagnosed with HIV in California achieved viral suppression, compared to 43% of White people (CHRP, 2014). When evaluating ARV use among Californian Medicaid and Medicare enrollees, Landovitz et al. (2017) found that a smaller proportion of Black Medi-Cal enrollees filled ARV prescriptions compared to White Medi-Cal enrollees (91% vs. 94%, respectively). Of these, less than half of Black people (46%) had health insurance coverage for ARV drugs for 330 days compared to 52% of White people. In sum, publicly insured Black people living with HIV in California had significantly lower odds of obtaining ARV drugs compared to publicly insured White people living with HIV (Landovitz et al., 2017).

Related to HIV treatment, disparities were also found in HIV linkages to care and viral suppression (CDPH, 2024). Compared to Latina (80%) and Asian (84%) women, American Indian/Alaska Native women had the lowest linkage to care (75%) within 1 month of HIV diagnosis followed by White and Black women (77% and 78%, respectively). Only 52% of White women achieved viral suppression in 6 months compared to 84% of Asian women (CDPH, 2024). Limited access to HIV care services, HIV-related stigma, and unmet needs (housing, transportation, and lack of childcare) were identified as barriers to treatment among Black and Latina women in the United States (Davy-Mendez et al., 2021; Geter et al., 2019).

#### Gender Identity or Sexual Orientation<sup>33</sup>

Of the subpopulations at highest risk for HIV, MSM — inclusive of gay, heterosexual, and bisexual men — experience disproportionate rates of HIV (HIV.gov, 2025).<sup>34</sup> In 2022, MSM accounted for 66% of the population living with HIV, and 55% of all new HIV diagnoses (CDPH, 2024b). Disparities among Black and Latino MSM newly diagnosed with HIV have increased between 2018 and 2022, primarily due a decrease in rates among White MSM (CDPH, 2024b). In 2022, Black MSM were 4.8 times more likely to be diagnosed with HIV compared to White MSM. Similarly, Latino MSM were approximately 3.3 times as likely to be diagnosed with HIV compared to White MSM (CDPH, 2024b). Moreover, Black MSM were found to have lower linkages to HIV care within one month of diagnosis and lower viral suppression within 6 months of HIV diagnosis compared to other race/ethnicities (CDPH, 2024b). For example, in 2022, 79% of Black MSM were linked to HIV care within one month of diagnosis compared to 84% of White MSM, 85% of Latino MSM and 95% of Asian MSM. Similarly, 63% of Black MSM achieved viral suppression within 6 months of HIV diagnosis compared to 72% among White MSM, 73% in Latino MSM, and 81% Asian MSM (CDPH, 2024b). Researchers attributed similar findings

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<sup>&</sup>lt;sup>32</sup> Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

<sup>&</sup>lt;sup>33</sup> CHBRP defines gender identity as one's internal sense of one's own gender, or the gender in which a person identifies, whether it be male, female, or nonbinary. Gender identity and sexual orientation are different facets of one's identity; an individual's gender does not determine a person's sexual orientation (i.e., a person's emotional, romantic, or sexual attraction to other people) (ACOG, 2022; CDC, 2022d).

<sup>&</sup>lt;sup>34</sup> Per the CDPH (2023), it is estimated that both transgender women and men also experience disproportionate rates of HIV. Among Californian transgender people newly diagnosed in 2022, 83% were among Latinx and Black/African Americans and 98% were among transgender women. Since 2018, the overall number of new HIV diagnoses among the transgender population has increased 42% (CDPH, 2024b).



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(i.e., lack of viral suppression) among Black MSM (33%) compared to White MSM (19%) among Black MSM residing in a Southern metropolitan area to factors associated with structural racism (e.g., having a lesser likelihood of being prescribed ARV drugs, greater likelihood of reporting side effects with ARV drugs, and intentionally stopping ARV drugs for 2 or more days within a 12-month period) (Beer et al., 2016; Sullivan et al., 2021).<sup>35</sup> Quinn and Voisin (2020) found that poor adherence to ARV drugs among Black MSM was associated with stigma (and homonegativity), exposure to violence and trauma, and higher levels of substance use.

#### Age

The overall rate of new HIV diagnoses among youth aged 13 to 24 years decreased by 20% between 2018 and 2022; however, in 2022, this population accounted for 16% of new HIV diagnoses (CDPH, 2024b). Although the rate of new diagnoses among cisgender males in this age range decreased by 23%, that of cisgender females of the same age increased by 7%. Black youth (13–24 years of age) had disproportionate health outcomes compared to other race/ethnicities (CDPH, 2024b). Black/African American youth had lower linkages to HIV care in one month (78%) compared to Asian youth (94%). In addition, sustained viral suppression was lower for Black youth (58%) in comparison to White (60%), Latinx (68%), and Asian (78%) youth (CDPH, 2024b). In San Francisco, 14% of the 223 new HIV cases were among 13-to-24-year-olds in 2016 — with young transgender women and MSM accounting for a majority of the cases (SFDPH, 2018). Similar to nationwide trends, young Californians living with HIV have poor outcomes across the continuum of HIV care (Trujillo et al., 2020). For example, only 63% of 13-to-24-year-olds newly diagnosed with HIV achieved viral suppression within 12 months after linkage to care in San Francisco (SFDPH, 2018).

#### **Barriers to Access and Use of Antiretrovirals**

#### **Barriers to Accessing PrEP**

Despite the effectiveness of PrEP in the prevention of HIV, numerous barriers to PrEP access and utilization among those at high risk for HIV have been identified. In a narrative review conducted by Mayer et al. (2020), seven key barriers to PrEP uptake by potential PrEP users were identified:

- Poor awareness and/or knowledge of PrEP among potential utilizers of PrEP;
- Low perception of HIV risk;
- Social stigma from primary care providers and/or family/partner/friends;<sup>36</sup>
- Distrust of providers and/or the health care system;
- Lack of access to medical care (e.g., transportation barriers, time constraints);
- · Lack of access to financial assistance; and
- Concerns about potential side effects associated with PrEP use.

In addition, Patel et al. (2017) cited lack of insurance coverage as a barrier to access and use of PrEP. In a multi-city (Jackson, Mississippi; St. Louis, Missouri; Providence, Rhode Island) evaluation of the impact of insurance coverage on utilization of PrEP within three clinics, Patel et al. (2017) found that insurance coverage was significantly associated with PrEP utilization. Of the 201 PrEP patients included in the evaluation, researchers found that insured patients were four times as likely to use PrEP services compared to the uninsured.

<sup>&</sup>lt;sup>35</sup> These findings are corroborated by those found in a recent California Health Care Foundation study entitled *Listening to Black Californians* (Cummings, 2022). From a large statewide survey of over 3,300 Black Californians, in addition to in-depth interviews, researchers found that racism and structural barriers in the health care system prevented Black Californians from achieving the health they wish to seek (Cummings, 2022).

<sup>&</sup>lt;sup>36</sup> Stigma can play a large role in preventing patient initiation of PrEP/PEP, in which both the patient and/or provider may contribute to a lack of discussion. Physicians may be reluctant to ask about sexual history and habits. Similarly, patients may be reluctant to share information for fear of being stigmatized or labeled (Miller, 2019).



#### **Barriers to Accessing PEP**

Similar to PrEP, a number of barriers to PEP use have been identified by the San Francisco AIDS Foundation (Holtz, 2020), including:

- Inequities in health care access (e.g., lack of insurance coverage, time constraints);
- Affordability/financial constraints, particularly among youth and adolescents and individuals on fixed incomes;
- Lack of widespread awareness surrounding PEP; and
- Stigma.

#### Barriers to Access and Adherence to ARV Drugs Among Individuals with HIV

Numerous barriers to accessing and sustaining engagement in HIV care among those disproportionately affected by HIV have been identified (Mizuno et al., 2022; Park et al., 2020; Philbin et al., 2016), including:

- HIV-related stigma;
- Lack of access to health care services;
- Poverty and/or financial constraints;
- Homelessness and/or housing instability;
- Lack of transportation;
- Low health literacy;
- HIV discrimination;
- Poor treatment experiences;
- Substance use;
- · Mental health diagnoses; and
- · Fear of confidentiality breaches.

In addition, specific to financial constraints, multiple studies found that increased cost sharing was associated with worse adherence, persistence, or discontinuation of medications altogether (Fusco et al., 2023; Johnston et al., 2012). For example, among a retrospective observational study using claims data among commercially insured HIV patients across the United States from 2002 to 2008, researchers found that the mean adherence (proportion of days covered by ARV regimen) ranged from 97% for cost-sharing levels in the bottom quintile (\$0 to \$20 per 30-day supply) compared to 94% for cost-sharing levels in the top quintile (\$84 to \$3,832 per 30-day supply) (Johnston et al., 2012).

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#### **Benefit Coverage, Utilization, and Cost Impacts**



# How does utilization impact premiums?

Health insurance, by design, distributes risk and expenditures across everyone enrolled in a plan or policy. It does so to help protect each enrollee from the full impact of health care costs that arise from that enrollee's use of prevention, diagnosis, and/or treatment of a covered medical condition, disease, or injury. Changes in utilization among any enrollees in a plan or policy can result in changes to premiums for all enrollees in that plan or policy.

As discussed in the *Policy Context* section, AB 554 would require nongrandfathered and grandfathered DMHC-regulated plans and CDI-regulated policies to cover FDA-approved or CDC-recommended ARV drugs, devices, and products for the prevention of HIV/AIDS, with no cost sharing or utilization review requirements. In addition, the bill language specifies that ARV drugs must not be subject to prior authorization, step therapy, or any other protocol designed to delay treatment. Coverage for all therapeutically equivalent versions of ARV drugs without prior authorization or step therapy (i.e., utilization management techniques) would not be required if at least one therapeutic equivalent ARV drug is covered without prior authorization, step therapy requirements, or cost sharing, pursuant to an exception request.

AB 554 would apply to large-group plans and policies of state-regulated insurance in the first year postmandate, and extend to include small-group and individual market insurance in the second year postmandate.

This section reports the potential incremental impacts of AB 554 on estimated baseline benefit coverage, utilization, and overall cost.

#### **Analytic Approach and Key Assumptions**

#### **Pharmacy versus Medical Benefit**

Almost all (96.2%) commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or

CDI that covers both generic and brand-name outpatient prescription medications.<sup>37</sup> Of the remaining commercial/CalPERS enrollees, 1.2% do not have a pharmacy benefit and 2.6% have a pharmacy benefit that is not regulated by DMHC or CDI. Because AB 554 does not require creation of a pharmacy benefit — only compliant benefit coverage when a pharmacy benefit is present — baseline benefit coverage for enrollees without a pharmacy benefit or whose pharmacy benefit is not regulated by DMHC or CDI is assumed to be compliant.

In general, drugs that are physician-ordered and administered under the supervision of a physician (generally in a hospital, a provider's office, infusion center, or similar medical facility), along with the hospital stay or office visit, are generally covered through the medical benefit. Pharmacy benefits typically cover outpatient prescription drugs by covering prescriptions that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy. The majority of ARV drugs are covered under the pharmacy benefit. However, long-acting injectable ARV drugs, such as cabotegravir and lenacapavir, are typically covered under the medical benefit.<sup>38</sup> For this analysis, CHBRP has investigated both medical and pharmacy benefit claims data from Milliman to determine utilization and unit costs at baseline.

#### **Furnishing ARV Drugs**

Oral PrEP and PEP are prescribed most often by a primary care provider and filled at a pharmacy. However, California law authorizes pharmacists to furnish PrEP (up to a 90-day supply) and PEP without a physician's prescription. CHBRP assumes that this practice will continue and that there will not be any change in providers who administer or furnish ARV drugs.

<sup>&</sup>lt;sup>37</sup> For more detail, see CHBRP's <u>resource</u> Pharmacy Benefit Coverage in State-Regulated Health Insurance.

<sup>&</sup>lt;sup>38</sup> The oral dosages for lenacapavir are typically covered under the pharmacy benefit.



#### **Postmandate Utilization**

In addition to prohibiting cost sharing for ARV drugs, devices, and products, AB 554 would disallow health plans and insurers from implementing utilization management practices, including prior authorization, step therapy, and utilization review for ARV drugs, devices, and products. In CHBRP's analysis of SB 427 (2023), the results of the medical literature review showed there is not enough research on the effect of cost sharing and utilization management for ARV drugs on health care utilization. Thus, it was necessary for CHBRP to make assumptions regarding postmandate utilization.

#### Year 1 (2026)

Although enrollees may gain access to ARV drugs on a shorter timeline if AB 554 was enacted, CHBRP assumed a 1% increase in utilization in the first year postmandate, driven primarily by new benefit coverage in grandfathered large-group plans.

#### Year 2 (2027)

In Year 2 postmandate, AB 554 would apply to the small-group and individual health plans and policies regulated by DMHC and CDI, respectively. CHBRP assumed a 1% increase in utilization driven by the elimination in cost sharing.

In addition, CHBRP assumed an increase in utilization due to the new medication. As described in the *Background on ARV Drugs* section, the FDA is expected to approve lenacapavir for use as PrEP in 2025. However, based on historical data on the introduction of other long-acting injectable drugs to the market, CHBRP estimates that lenacapavir will not be readily available until 2027.<sup>39</sup> CHBRP anticipates that uptake of lenacapavir will increase overall utilization of ARV drugs in Year 2 because of interest in a PrEP regimen that requires a lower frequency of doses to maintain. Should the FDA's approval of lenacapavir for use as PrEP be delayed or not occur, fiscal impacts would be lower in the second year postmandate. Should approval occur earlier than anticipated in 2025, fiscal impacts may be higher in Year 2. Changes in the drug's time to market would also impact fiscal estimates. Following Year 2, utilization may be similar to that of other long-acting injectables during the first years they were available on the market.

#### Cost offsets

Although additional use of and adherence to ARV drugs will prevent HIV infection and later AIDS-related diseases, the marginal impact of AB 554 over the existing use of ARV drugs cannot be quantified. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to AB 554.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

#### **Baseline and Postmandate Benefit Coverage**

As discussed in the *Policy Context* section, in the first year postmandate, AB 554 would apply to the large-group market of state-regulated health insurance, including commercial enrollees and enrollees with insurance through CalPERS. Exempt insurance includes that of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. It should be noted that DMHC regulates the plans of approximately 74% of enrollees associated with CalPERS, and 80% of Medi-Cal beneficiaries, in addition to commercial enrollees. <sup>40</sup> In the second year postmandate, DMHC-regulated plans and CDI-regulated policies in the small-group and individual markets would become subject to AB 554.

<sup>&</sup>lt;sup>39</sup> Communication with J. Cocohoba, MD, March 2025.

<sup>&</sup>lt;sup>40</sup> For more detail, see CHBRP's resource Sources of Health Insurance in California.



#### Year 1

CHBRP estimates that at baseline, approximately 8,794,000 (95.5%) Californians are enrolled in large-group plans or policies that are fully compliant with AB 554 and have coverage for ARV drugs without cost sharing. Postmandate, 100% of enrollees with large-group health insurance subject to AB 554 would have coverage for ARV drugs, devices, and products without cost sharing.

Below, Table 3 provides estimates of how many Californians have health insurance that would have to comply with AB 554 in terms of benefit coverage in Year 1.

Table 3. Impacts of AB 554 on Benefit Coverage, 2026

	Baseline	Postmandate	Increase/Decrease	Percentage Change
Total enrollees with health insurance subject to state benefit mandates (a)	22,207,000	22,207,000	0	0.00%
Total enrollees with health insurance subject to AB 554 (b)	9,212,000	9,212,000	0	0.00%
Number of enrollees with noncompliant coverage for ARV drugs	223,000	0	(223,000)	-100.00%
Number of enrollees with partially compliant coverage for ARV drugs	195,000	0	(195,000)	-100.00%
Number of enrollees with fully compliant coverage for mandated benefit	8,794,000	9,212,000	418,000	4.75%

#### Source: California Health Benefits Review Program, 2025.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal. <sup>41</sup> (b) In the first year postmandate, AB 554 would only apply to the large-group market in DMHC-regulated plans and CDI-regulated policies. In the second year postmandate, AB 554 DMHC-regulated plans and CDI-regulated policies in the small-group and individual markets would become subject to the mandate. For more information on the Year 2 impacts, see Appendix C.

Key: ARV = antiretroviral; CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

#### Year 2

In Year 2 postmandate, when plans and policies in the small-group and individual markets would be required to comply, an increase in 4.98% of the enrollee population would gain coverage for the use of ARV drugs without cost sharing, compared to baseline. See Appendix C for more details.

#### **Baseline and Postmandate Utilization and Unit Cost**

#### Year 1

At baseline, CHBRP estimates 63,155 enrollees in the large-group market utilize ARV drugs each year, about half (53.5%) of whom also have cost sharing (Table 4). Approximately 30% (10,378 enrollees) of those that utilize ARV drugs with cost sharing will reach their annual maximum out-of-pocket limit partway through the year and experience no cost sharing for the remainder of the year. Because of this, there is some overlap between the population of enrollees utilizing ARV drugs with and without cost sharing in Table 4 below. Postmandate, CHBRP estimates approximately 25,079 additional enrollees will utilize ARV drugs without cost sharing.

<sup>&</sup>lt;sup>41</sup> For more detail, see CHBRP's resource Sources of Health Insurance in California.



On average, each enrollee who utilizes ARV drugs and has cost sharing at baseline has 6.9 prescriptions filled for ARV drugs. Note that the average number of filled prescriptions per enrollee was determined using the populations of "with cost sharing" and "without cost sharing" respectively, and did not take the overlapping number of enrollees into account in either ratio. The 6.9 figure for prescriptions filled for ARV drugs excludes prescriptions for which the enrollee would have had cost sharing but met their annual out-of-pocket maximum. In total, CHBRP estimates 235,108 prescriptions are filled for enrollees who utilize ARV drugs and have cost-sharing requirements.

CHBRP estimated the total average annual cost and average annual cost sharing based on the total annual cost of an ARV regimen; the data presented do not include the costs associated with additional treatments or the potential costs of complications or side effects. At baseline, the average annual cost of ARV drugs with cost sharing is \$19,318, with an annual cost share of \$1,273. Enrollees without cost sharing for ARV drugs at baseline have an average cost at baseline for ARV drugs of \$8,364. There is a cost difference between enrollees with and without cost sharing due to a combination of factors, including fewer prescriptions for those without cost sharing at baseline, and coverage of different types of ARV drugs, such as a low-cost generic version of Truvada. Postmandate, CHBRP estimates the average annual cost of ARV drugs would be \$15,617, with no enrollee cost sharing. CHBRP assumed that the average cost per prescription would not change as a result of AB 554; therefore, the postmandate average annual cost of ARV drugs reflects the total cost of ARV drugs divided among the postmandate population of eligible enrollees.

Baseline costs and utilization were based on Milliman data. CHBRP does not anticipate that AB 554 would impact unit cost postmandate.

Below, Table 4 provides estimates of the impacts of AB 554 on utilization and unit cost of ARV drugs.

Table 4. Impacts of AB 554 on Utilization and Unit Cost, 2026

	Baseline (2026)	Postmandate Year 1 (2026)	Increase/Decrease	Percentage Change
Number of enrollees using ARV drugs				
Number of enrollees using ARV drugs	63,155	64,721	1,566	2.48%
Number of enrollees using ARV drugs with cost sharing	33,890	0	-33,890	-100.00%
Number of enrollees using ARV drugs without cost sharing	39,643	64,721	25,079	63.26%
Prescriptions per user of ARV drugs with cost sharing	6.9	0	-6.9	-100.00%
Prescriptions per user of ARV drugs without cost sharing	5.1	7.0	1.8	35.08%
Percentage of enrollees using ARV drugs with cost sharing	0.4%	0.0%	-0.4%	-100.00%
Percentage of enrollees using ARV drugs without cost sharing	0.4%	0.7%	0.3%	59.31%
Utilization				



	Baseline (2026)	Postmandate Year 1 (2026)	Increase/Decrease	Percentage Change
ARV drug prescriptions with cost sharing	235,108	0	-235,108	-100.00%
ARV drug prescriptions without cost sharing	204,084	450,084	246,000	120.54%
% of utilization with cost sharing	53.5%	0.0%	-53.5%	-100.00%
% of Utilization without cost sharing	46.5%	100.0%	53.5%	115.20%
Average annual cost (a)				
ARV drugs with cost sharing	\$19,318	\$0	-\$19,318	-100.00%
ARV drugs without cost sharing	\$8,364	\$15,617	\$7,252	86.71%
Average annual cost sharing (a)				
ARV drugs with cost sharing	\$1,273	\$0	-\$1,273	-100.00%
ARV drugs without cost sharing	\$0	\$0	\$0	0.00%

#### Source: California Health Benefits Review Program, 2025.

Notes: Estimates related to prescriptions are for prescriptions filled, which is inclusive of first fills and refills for the year.

(a) Average annual cost and average annual cost sharing refer to the annual cost of an ARV regimen. Additional treatments and potential costs of complications or side effects are not included.

Key: ARV = antiretroviral.

#### Year 2

As previously discussed, utilization of ARV drugs would increase in Year 2 due to the increase in enrollees with health insurance subject to AB 554, and the anticipated availability of lenacapavir as an FDA-approved drug indicated for PrEP. CHBRP estimates that 96,753 enrollees would utilize ARV drugs, without cost sharing, in Year 2 postmandate. This represents an approximately 62% increase from baseline.

CHBRP assumed there would be no change in the average number of filled prescriptions per enrollees between Years 1 and 2. In total, CHBRP estimates an additional 363,600 prescriptions would be filled without cost sharing for ARV drugs compared to baseline.

See Appendix C for more details.



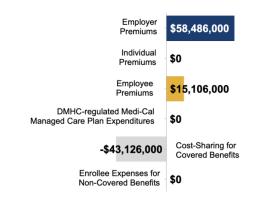
#### **Baseline and Postmandate Expenditures**

#### Year 1

For large-group commercial/CalPERS DMHC-regulated plans and CDI-regulated policies, AB 554 would increase total premiums paid by employers and enrollees for newly covered benefits by \$73,592,000 in Year 1. Enrollee expenses for covered and/or noncovered benefits would decrease by \$43,126,000 as a result of the prohibition on cost sharing. This would result in an increase of total net annual expenditures of \$30,466,000 (0.02%) for enrollees with large-group commercial/CalPERS DMHC-regulated plans and CDI-regulated policies (Error! Reference source not found.).

Below, Table 5 provides estimates of the impacts of AB 554 on expenditures in Year 1, which include premiums, enrollee cost sharing, and enrollee expenses for noncovered benefits.

Figure 3. Expenditure Impacts of AB 554 (Year 1)



Source: California Health Benefits Review Program, 2025. Key: DMHC = Department of Managed Health Care.

Table 5. Impacts of AB 554 on Expenditures, 2026

	Baseline	Postmandate	Increase/Decrease	Percentage Change
Premiums				
Employer-sponsored (a)	\$68,752,638,000	\$68,805,200,000	\$52,562,000	0.08%
CalPERS employer (b)	\$7,881,873,000	\$7,887,797,000	\$5,924,000	0.08%
Medi-Cal (excludes COHS) (c)	\$31,818,731,000	\$31,818,731,000	\$0	0.00%
Enrollee premiums				
Enrollees, individually purchased insurance	\$21,757,790,000	\$21,757,790,000	\$0	0.00%
Outside Covered California	\$6,011,399,000	\$6,011,399,000	\$0	0.00%
Through Covered California	\$15,746,391,000	\$15,746,391,000	\$0	0.00%
Enrollees, group insurance (d)	\$21,712,866,000	\$21,727,972,000	\$15,106,000	0.07%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copays, etc.)	\$18,992,422,000	\$18,949,296,000	-\$43,126,000	-0.23%
Expenses for noncovered benefits (e)	\$0	\$0	\$0	0.00%
Total expenditures	\$170,916,320,000	\$170,946,786,000	\$30,466,000	0.02%

Source: California Health Benefits Review Program, 2025.

Notes: (a) In some cases, a union or other organization. Excludes CalPERS.



(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.<sup>42</sup> CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(d) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

(e) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

#### Year 2

In Year 2, AB 554 would newly apply to the health insurance of enrollees in small-group and individual market plans and policies regulated by DMHC or CDI. For commercial/CalPERS DMHC-regulated plans and CDI-regulated policies, AB 554 would increase total premiums paid by employers and enrollees for newly covered benefits by \$135,988,000 in Year 2 compared to baseline. Enrollee expenses for covered and/or noncovered benefits would decrease by \$98,901,000 (0.48%) as a result of the prohibition on cost sharing. This would result in an increase of total net annual expenditures of \$37,087,000 (0.02%) for enrollees with DMHC-regulated plans and CDI-regulated policies in Year 2 compared to baseline. Additional details follow in the sections below.

#### **Premiums**

At the end of this section, Table 7 and Table 8 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies in Year 1. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

Changes in premiums as a result of AB 554 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 3, Table 7, and Table 8), with health insurance that would be subject to AB 554.

See additional information about impacts of AB 554 in Year 2 in Appendix C.

#### Commercial

In Year 1, CHBRP estimates that AB 554 would increase premiums for DMHC-regulated large-group plans by \$0.66 PMPM (0.09%), and by \$0.93 PMPM (0.11%) in CDI-regulated large-group plans. The total premium impacts for employer-sponsored insurance would increase by \$52,562,000 (0.08%) compared to baseline. Enrollee premiums would increase by \$15,106,000 (0.07%). Note that these impacts would only be due to effects on the large-group market, as the bill only applies to this market in Year 1.

In Year 2, when AB 554 would also apply to the small-group and individual markets, CHBRP estimates total premiums paid by employers would increase by approximately \$74,193,000 (0.10%) compared to baseline. Enrollee premiums would increase by \$23,774,000 (0.10%) compared to baseline for group insurance, and \$31,840,000 (0.13%) for insurance purchased in the individual market.

#### **CalPERS**

In Year 1, for enrollees associated with CalPERS in DMHC-regulated plans, CHBRP estimates premiums would increase by \$0.64 PMPM. In total, premiums would increase by approximately \$5,924,000 (0.08%) compared to baseline.

<sup>&</sup>lt;sup>42</sup> For more detail, see CHBRP's resource Pharmacy Benefit Coverage in State-Regulated Health Insurance.



In Year 2, premiums would increase by a total of \$6,181,000 (0.07%) for enrollees associated with CalPERS in DMHC-regulated plans compared to baseline.

#### Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be no impact because these plans are excluded from the bill mandate.

#### **Enrollee Expenses**

AB 554—related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 3, Table 7, and Table 8) with health insurance that would be subject to AB 554 expected to use ARV drugs during the year after enactment.

Although it is possible that some enrollees may have incurred expenses related to ARV drugs for which coverage was denied, CHBRP cannot estimate the frequency with which such situations occur and therefore cannot provide an impact calculation.

In Year 1, CHBRP estimates that the postmandate decrease in enrollee expenses due to the elimination of cost sharing will be \$0.38 PMPM for enrollees in DMHC-regulated large-group plans, \$0.40 PMPM for those with insurance regulated by CalPERS, and \$0.61 PMPM for those in CDI-regulated large-group policies. In total, enrollees in large-group DMHC-and CDI-regulated health plans and policies would see a reduction in cost sharing of \$43,126,000 (0.23%) compared to baseline.

In Year 2, CHBRP estimates the total impact on cost sharing would be a decrease of \$98,901,000 (0.48%) in comparison with baseline.

#### Average enrollee out-of-pocket expenses per user

For enrollees with coverage for ARV drugs at baseline, 33,890 enrollees would experience an average decrease in cost sharing of \$1,273 in Year 1 postmandate. In addition, 222,945 enrollees would have new benefit coverage due to AB 554. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to plans and insurers negotiating discounted rates that are unavailable to patients and their families.

Table 6. Impact of AB 554 on Average Enrollee Out-of-Pocket Expenses, 2026

	Large Group	Small Group	Individual	CalPERS	Medi-Cal (b)
Enrollees with baseline benefit coverage	8,904,741	0	0	894,314	0
% of enrollees with out-of-pocket expenses impact due to AB 554 (a)	0.37%	N/A	N/A	0.37%	N/A
Average annual out-of-pocket expenses impact for enrollees	(\$1,271)	N/A	N/A	(\$1,289)	N/A
Enrollees with new benefit coverage	203,259	0	0	19,686	0
% of enrollees with out-of-pocket expenses impact due to AB 554 (a)	0%	N/A	N/A	0.00%	N/A



Average annual out-of-pocket expenses impact	\$0.00	N/A	N/A	\$0.00	N/A
for enrollees					

Source: California Health Benefits Review Program, 2025.

Notes: Average enrollee out-of-pocket expenses include cost sharing (e.g., deductibles, copayments, and coinsurance) and out-of-pocket expenses for noncovered benefits. Small-group and individual plans and policies are not subject to AB 554 until 2027.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries is not subject to AB 554.

Key: CalPERS = California Public Employees' Retirement System.

The presence of a deductible not yet met for the year<sup>43</sup> could result in the enrollee paying the full unit cost; however, hitting the annual out-of-pocket maximum<sup>44</sup> would result in the enrollee having no further cost sharing.

In Year 2, 50,893 enrollees would experience an average decrease in cost sharing of \$1,943 compared to baseline. In addition, 232,522 enrollees would have new benefit coverage due to AB 554. See Table 13 in Appendix C for more details.

#### **Postmandate Administrative and Other Expenses**

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

The increased utilization of PrEP projected by CHBRP as a result of AB 554 would likely increase utilization of tests and services related to HIV testing and sexually transmitted infections. The CDC currently recommends testing for sexually transmitted infections every 3 to 6 months for those taking PrEP (CDC, 2024c). CHBRP was unable to estimate these additional costs.

#### **Other Considerations for Policymakers**

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

#### **Postmandate Changes in the Number of Uninsured Persons**

Because the change in average premiums does not exceed 1% for any market segment (see Table 5, Table 7, and Table 8), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 554.

#### **Changes in Public Program Enrollment**

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 554.

#### How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

There does not appear to be cost shifting to other public payers or programs at baseline.

<sup>&</sup>lt;sup>43</sup> For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource Deductibles in State-Regulated Health Insurance.

<sup>&</sup>lt;sup>44</sup> For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to \$250, or \$500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (HSC 1342.73; INS 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.



#### **Long-Term Utilization and Cost Impacts**

Cost impacts over the long term would be proportional to any increase in utilization. New ARV drugs, devices, and products that may be developed in the future could have additional impacts on utilization in the long-term. However, as discussed in the *Background* section, cost is not the only barrier to access to ARV drugs. Provider awareness, stigma, inequities in healthcare access, and low perception of risk also create challenges that impact ARV drug utilization, and ultimately the incidence and prevalence of HIV/AIDS.

As previously stated, although additional use of and adherence to ARV drugs will prevent HIV infection and later AIDS-related diseases, the marginal impact of AB 554 over the existing use of ARV drugs cannot be quantified. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to AB 554.



Table 7. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2026

	DMHC-Regulated									
	Commercia	al Plans (by M	arket) (a)	Pub	licly Funded Pla	ıns	Commercia	l Policies (by		
	Large Group	Small Group	Individual	CaIPERS (b)	Medi- (Excludes C		Large Group	Small Group	Individual	Total
					Under 65	65+				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,034,000	2,076,000	2,181,000	914,000	7,787,000	850,000	264,000	65,000	36,000	22,207,000
Total enrollees in plans/policies subject to AB 554	8,034,000	0	0	914,000	0	0	264,000	0	0	9,212,000
Premiums										
Average portion of premium paid by employer (e)	\$557.33	\$507.76	\$0.00	\$718.62	\$276.79	\$583.72	\$609.11	\$567.83	\$0.00	\$108,453,242,000
Average portion of premium paid by enrollee	\$145.58	\$212.63	\$818.51	\$139.09	\$0.00	\$0.00	\$224.25	\$185.49	\$777.47	\$43,470,656,000
Total premium	\$702.91	\$720.39	\$818.51	\$857.71	\$276.79	\$583.72	\$833.35	\$753.32	\$777.47	\$151,923,898,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$64.42	\$164.36	\$272.54	\$81.59	\$0.00	\$0.00	\$122.99	\$249.30	\$173.93	\$18,992,422,000
Expenses for noncovered benefits (f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$767.33	\$884.75	\$1,091.05	\$939.30	\$276.79	\$583.72	\$956.34	\$1,002.63	\$951.40	\$170,916,320,000

#### Source: California Health Benefits Review Program, 2025.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

- (b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.<sup>45</sup> CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).
- (c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.
- (d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal. 46
- (e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

<sup>(</sup>f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

<sup>&</sup>lt;sup>45</sup> For more detail, see CHBRP's resource Estimates of Pharmacy Benefit Coverage in State-Regulated Health Insurance.

<sup>&</sup>lt;sup>46</sup> For more detail, see CHBRP's resource Sources of Health Insurance in California.



Table 8. Postmandate Change in Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2026

I	DMHC-Regulated									
l l	Commercia	al Plans (by M	arket) (a)	Publ	icly Funded Pla	ns	Commercia			
	Large Group	Small Group	Individual	CaIPERS (b)	Medi- (Excludes C Under 65		Large Group	Small Group	Individual	Total
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,034,000	2,076,000	2,181,000	914,000	7,787,000	850,000	264,000	65,000	36,000	22,207,000
Total enrollees in plans/policies subject to AB 554	8,034,000	0	0	914,000	0	0	264,000	0	0	9,212,000
Premiums										
Average portion of premium paid by employer (e)	\$0.5229	\$0.0000	\$0.0000	\$0.5401	\$0.0000	\$0.0000	\$0.6775	\$0.0000	\$0.0000	\$58,486,000
Average portion of premium paid by enrollee	\$0.1366	\$0.0000	\$0.0000	\$0.1045	\$0.0000	\$0.0000	\$0.2494	\$0.0000	\$0.0000	\$15,106,000
Total premium	\$0.6595	\$0.0000	\$0.0000	\$0.6447	\$0.0000	\$0.0000	\$0.9269	\$0.0000	\$0.0000	\$73,592,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	-\$0.3823	\$0.0000	\$0.0000	-\$0.3962	\$0.0000	\$0.0000	-\$0.6082	\$0.0000	\$0.0000	-\$43,126,000
Expenses for noncovered benefits (f)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.2773	\$0.0000	\$0.0000	\$0.2485	\$0.0000	\$0.0000	\$0.3187	\$0.0000	\$0.0000	\$30,466,000
Postmandate Percent Change										
Percent change insured premiums	0.0938%	0.0000%	0.0000%	0.0752%	0.0000%	0.0000%	0.1112%	0.0000%	0.0000%	0.0484%
Percent change total expenditures	0.0361%	0.0000%	0.0000%	0.0265%	0.0000%	0.0000%	0.0333%	0.0000%	0.0000%	0.0178%

#### Source: California Health Benefits Review Program, 2025.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

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<sup>(</sup>b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.<sup>47</sup> CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

<sup>(</sup>c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

<sup>(</sup>d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal. 48

<sup>(</sup>e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.

<sup>(</sup>f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

<sup>&</sup>lt;sup>47</sup> For more detail, see CHBRP's <u>resource</u> Pharmacy Benefit Coverage in State-Regulated Health Insurance.

<sup>&</sup>lt;sup>48</sup> For more detail, see CHBRP's resource Sources of Health Insurance in California.



#### **Appendix A. Text of Bill Analyzed**

On February 24, 2025, the California Assembly Committee on Health requested that CHBRP analyze AB 554 as amended on March 3, 2025.

AMENDED IN ASSEMBLY MARCH 03, 2025

CALIFORNIA LEGISLATURE— 2025-2026 REGULAR SESSION

Assembly Bill No. 554

Introduced by Assembly Member Mark González Members Mark González and Haney
(Principal coauthor: Senator Wiener)
(Coauthors: Assembly Members Jackson and Ward)

February 11, 2025

An act to amend, repeal, and add Section 1342.74 of the Health and Safety Code, and to amend, repeal, and add Section 10123.1933 of the Insurance Code, relating to health care coverage.

#### LEGISLATIVE COUNSEL'S DIGEST

AB 554, as amended, Mark González. Health care coverage: antiretroviral drugs, drug devices, and drug products.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law generally prohibits a health care service plan, excluding a Medi-Cal managed care plan, or health insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of HIV/AIDS, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy. Under existing law, a health care service plan or health insurer is not required to cover all the therapeutically equivalent versions of those drugs without prior authorization or step therapy if at least one is covered without prior authorization or step therapy.

This bill, the Protecting Rights, Expanding Prevention, and Advancing Reimbursement for Equity (PrEPARE) Act of 2025, would instead prohibit a health care service plan, excluding a Medi-Cal managed care plan, or health insurer from subjecting antiretroviral drugs, drug devices, or drug products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of HIV/AIDS, to prior authorization or step therapy, prior authorization, step therapy, or any other protocol designed to delay treatment, but would authorize prior authorization or step therapy if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the plan or insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request. The bill would specify that, for therapeutically equivalent coverage purposes, a long-acting injectable



drug is not therapeutically equivalent to a long-acting injectable drug with a different duration. The bill would require a plan or insurer to provide coverage under the outpatient prescription drug benefit for those drugs, drug devices, or drug products, including by supplying participating providers directly with a drug, drug device, or drug product, as specified.

This bill would require a nongrandfathered or grandfathered health care service plan contract or health insurance policy to provide coverage for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, and would prohibit a nongrandfathered or grandfathered health care service plan contract or health insurance policy from imposing any cost-sharing or utilization review requirements for those drugs, drug devices, or drug products. The bill would exempt Medi-Cal managed care plans from these provisions and would delay the application of these provisions for an individual and small group health care service plan contract or health insurance policy until January 1, 2027.

Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

Existing law requires a health care service plan or health insurer to cover preexposure prophylaxis or postexposure prophylaxis that has been furnished by a pharmacist, as specified. Existing law prohibits a health care service plan or health insurer from prohibiting a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

This bill would delete the requirement for a health care service plan or health insurer to cover postexposure prophylaxis that has been furnished by a pharmacist. The bill would delete the provisions that prohibit a health care service plan or health insurer from prohibiting a pharmacy provider from dispensing postexposure prophylaxis.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

#### **DIGEST KET**

Vote: MAJORITY Appropriation: NO Fiscal Committee: YES Local Program: YES

**BILL TEXT** 

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** This act shall be known, and may be cited, as the Protecting Rights, Expanding Prevention, and Advancing Reimbursement for Equity (PrEPARE) Act of 2025.

**SECTION 1.-SEC. 2.** Section 1342.74 of the Health and Safety Code is amended to read:

**1342.74.** (a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs, drug devices, or drug products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of HIV/AIDS, including preexposure prophylaxis, to prior authorization or step therapy, prophylaxis or postexposure prophylaxis, to prior authorization, step therapy, or any other protocol designed to delay treatment, except as provided in paragraph (2).

(2) If the FDA has approved one or more therapeutic equivalents of a drug, drug device, or drug product for the prevention of HIV/AIDS, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the plan provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request. For purposes of this section, a long-acting injectable drug is not therapeutically equivalent to a long-acting injectable drug with a different duration.



- (b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure *prophylaxis or postexposure* prophylaxis.
- (c) A health care service plan shall cover preexposure prophylaxis and postexposure prophylaxis that has been furnished by a pharmacist, as authorized in-Section 4052.02 Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health care service plan shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health care service plan has an out-of-network pharmacy benefit.
- (d) This section does not require a health care service plan to cover preexposure prophylaxis *or postexposure prophylaxis* by a pharmacist at an out-of-network pharmacy, unless in the case of an emergency or if the health care service plan has an out-of-network pharmacy benefit.
- (e) (1) A nongrandfathered health care service plan contract shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (2) A health care service plan contract that is a grandfathered health plan shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (3) This subdivision does not apply to individual and small group health care service plan contracts.
- (f) In addition to the coverage a health care service plan provides for prescription drugs that are not self-administered, a health care service plan shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, drug device, or drug product that is required by this section and is not self-administered.
- (g) (1) This section does not apply to a specialized health care service plan contract that covers only dental or vision benefits or a Medicare supplement contract.
  - (2) This section applies regardless of whether or not an antiretroviral drug, drug device, or drug product is self-administered.
  - (3) This section shall not apply to Medi-Cal managed care plans contracting with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14590) of Part 3 of Division 9 of the Welfare and Institutions Code, to the extent that the services described in this section are excluded from coverage under the contract between the Medi-Cal managed care plans and the State Department of Health Care Services.
- (h) A health care service plan contract that is a high deductible health plan under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code shall comply with the cost-sharing requirements of this section. However, if not applying the minimum annual deductible to an antiretroviral drug, drug device, or drug product would conflict with federal requirements for high deductible health plans, the cost-sharing limits shall apply once a contract's deductible has been satisfied for the plan year.
- (i) This section shall remain in effect only until January 1, 2027, and as of that date is repealed.
- SEC. 2. SEC. 3. Section 1342.74 is added to the Health and Safety Code, to read:
- **1342.74.** (a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs, drug devices, or drug products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of HIV/AIDS, including



preexposure prophylaxis, to prior authorization or step therapy, propyhlaxis or postexposure prophylaxis, to prior authorization, step therapy, or any other protocol designed to delay treatment, except as provided in paragraph (2).

- (2) If the FDA has approved one or more therapeutic equivalents of a drug, drug device, or drug product for the prevention of HIV/AIDS, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the plan provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request. For purposes of this section, a long-acting injectable drug is not therapeutically equivalent to a long-acting injectable drug with a different duration.
- (b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure *prophylaxis or postexposure* prophylaxis.
- (c) A health care service plan shall cover preexposure prophylaxis and postexposure prophylaxis that has been furnished by a pharmacist, as authorized in-Section 4052.02 Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health care service plan shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health care service plan has an out-of-network pharmacy benefit.
- (d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless in the case of an emergency or if the health care service plan has an out-of-network pharmacy benefit.
- (e) (1) A nongrandfathered health care service plan contract shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (2) A health care service plan contract that is a grandfathered health plan shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
- (f) In addition to the coverage a health care service plan provides for prescription drugs that are not self-administered, a health care service plan shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, drug device, or drug product that is required by this section and is not self-administered.
- (g) (1) This section does not apply to a specialized health care service plan contract that covers only dental or vision benefits or a Medicare supplement contract.
  - (2) This section applies regardless of whether or not an antiretroviral drug, drug device, or drug product is self-administered.
  - (3) This section shall not apply to Medi-Cal managed care plans contracting with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14590) of Part 3 of Division 9 of the Welfare and Institutions Code, to the extent that the services described in this section are excluded from coverage under the contract between the Medi-Cal managed care plans and the State Department of Health Care Services.
- (h) A health care service plan contract that is a high deductible health plan under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code shall comply with the cost-sharing requirements of this section. However, if not applying the minimum annual deductible to an antiretroviral drug, drug device, or drug product would conflict with



federal requirements for high deductible health plans, the cost-sharing limits shall apply once a contract's deductible has been satisfied for the plan year.

(i) This section shall become operative on January 1, 2027.

SEC. 3. SEC. 4. Section 10123.1933 of the Insurance Code is amended to read:

- **10123.1933.** (a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs, drug devices, or drug products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of HIV/AIDS, including preexposure prophylaxis, to prior authorization or step therapy, prophylaxis or postexposure prophylaxis, to prior authorization, step therapy, or any other protocol designed to delay treatment, except as provided in paragraph (2).
  - (2) If the FDA has approved one or more therapeutic equivalents of a drug, drug device, or drug product for the prevention of HIV/AIDS, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request. For purposes of this section, a long-acting injectable drug is not therapeutically equivalent to a long-acting injectable drug with a different duration.
- (b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure *prophylaxis or postexposure* prophylaxis.
- (c) A health insurer shall cover preexposure *prophylaxis or postexposure* prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health insurer shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health insurer has an out-of-network pharmacy benefit.
- (d) This section does not require a health insurer to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless in the case of an emergency or if the health insurance policy has an out-of-network pharmacy benefit.
- (e) (1) A nongrandfathered health insurance policy shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (2) A health insurance policy that is a grandfathered health plan shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (3) This subdivision does not apply to individual and small group health insurance policies.
- (f) In addition to the coverage a health insurer provides for prescription drugs that are not self-administered, a health insurer shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, drug device, or drug product that is required by this section and is not self-administered.
- (g) (1) This section does not apply to a specialized health insurance policy that covers only dental or vision benefits or a Medicare supplement policy.
  - (2) This section applies regardless of whether or not an antiretroviral drug, drug device, or drug product is self-administered.



- (h) The department and commissioner may exercise the authority provided by this code and the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) to implement and enforce this section. If the commissioner assesses a civil penalty for a violation, any hearing that is requested by the insurer may be conducted by an administrative law judge of the administrative hearing bureau of the department under the formal procedure of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. This subdivision does not impair or restrict the commissioner's authority pursuant to another provision of this code or the Administrative Procedure Act.
- (i) A health insurance policy that is a high deductible health plan under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code shall comply with the cost-sharing requirements of this section. However, if not applying the minimum annual deductible to an antiretroviral drug, drug device, or drug product would conflict with federal requirements for high deductible health plans, the cost-sharing limits shall apply once a policy's deductible has been satisfied for the plan year.
- (j) This section shall remain in effect only until January 1, 2027, and as of that date is repealed.

SEC. 4. SEC. 5. Section 10123.1933 is added to the Insurance Code, to read:

- **10123.1933**. (a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs, drug devices, or drug products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of HIV/AIDS, including preexposure prophylaxis, to prior authorization or step therapy, prophylaxis or postexposure prophylaxis, to prior authorization, step therapy, or any other protocol designed to delay treatment, except as provided in paragraph (2).
  - (2) If the FDA has approved one or more therapeutic equivalents of a drug, drug device, or drug product for the prevention of HIV/AIDS, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request. For purposes of this section, a long-acting injectable drug is not therapeutically equivalent to a long-acting injectable drug with a different duration.
- (b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure *prophylaxis or postexposure* prophylaxis.
- (c) A health insurer shall cover preexposure prophylaxis or postexposure prophylaxis that has been furnished by a pharmacist, as authorized in—Section 4052.02 Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health insurer shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health insurer has an out-of-network pharmacy benefit.
- (d) This section does not require a health insurer to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless in the case of an emergency or if the health insurance policy has an out-of-network pharmacy benefit.
- (e) (1) A nongrandfathered health insurance policy shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.
  - (2) A health insurance policy that is a grandfathered health plan shall provide coverage, and shall not impose any cost-sharing or utilization review requirements, for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including preexposure prophylaxis.



- (f) In addition to the coverage a health insurer provides for prescription drugs that are not self-administered, a health insurer shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, drug devices, or drug products that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, drug device, or drug product that is required by this section and is not self-administered.
- (g) (1) This section does not apply to a specialized health insurance policy that covers only dental or vision benefits or a Medicare supplement policy.
  - (2) This section applies regardless of whether or not an antiretroviral drug, drug device, or drug product is self-administered.
- (h) The department and commissioner may exercise the authority provided by this code and the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) to implement and enforce this section. If the commissioner assesses a civil penalty for a violation, any hearing that is requested by the insurer may be conducted by an administrative law judge of the administrative hearing bureau of the department under the formal procedure of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. This subdivision does not impair or restrict the commissioner's authority pursuant to another provision of this code or the Administrative Procedure Act.
- (i) A health insurance policy that is a high deductible health plan under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code shall comply with the cost-sharing requirements of this section. However, if not applying the minimum annual deductible to an antiretroviral drug, drug device, or drug product would conflict with federal requirements for high deductible health plans, the cost-sharing limits shall apply once a policy's deductible has been satisfied for the plan year.
- (i) This section shall become operative on January 1, 2027.

**SEC. 5.** SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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# **Appendix B. Cost Sharing and Utilization Management**

This section provides an overview of the cost-sharing and utilization management structures used for health insurance benefits, including prescription drugs.

## **Cost Sharing**

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses<sup>49</sup>). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 4). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.<sup>50</sup>

Annual out-of-pocket maximums for covered benefits limit annual enrollee cost sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

An enrollee using ARV drugs may experience multiple forms of out-of-pocket expenses. If an enrollee has a plan with a deductible, and the enrollee has not yet met the deductible, the enrollee would be responsible for the full cost of care and prescriptions until that deductible is met. Once an enrollee has met their deductible, the enrollee would be responsible for the copayment or coinsurance associated with the ARV prescriptions. Should an enrollee's out-of-pocket expenses meet the annual out-of-pocket maximum, the enrollee would no longer be responsible for cost-sharing obligations.

AB 554 would instead prohibit all forms of cost sharing, including copayments, coinsurance, and deductibles. The enrollee would still be responsible for any noncovered expenses.

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within the required actuarial value limits.

 <sup>&</sup>lt;sup>49</sup> Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through Covered California, or they receive benefits through Medi-Cal.
 <sup>50</sup> Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design



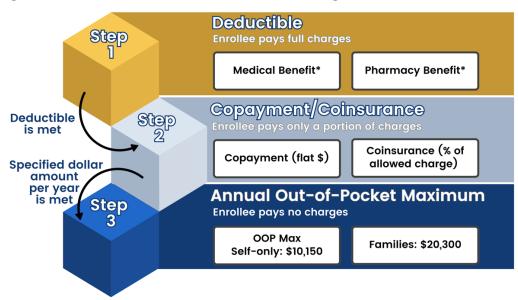


Figure 4. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance

Notes: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2). The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2024).

\*There is variation in the type and source of the pharmacy benefit among commercial and CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. While most enrollees have a pharmacy benefit that is regulated by DMHC or CDI, a small share of enrollees in the individual market have a pharmacy benefit that covers only generic medications, do not have a pharmacy benefit at all, or have a pharmacy benefit not subject to DMHC or CDI regulation. Thus, the deductible paid by enrollees will vary depending on whether they have a medical and/or pharmacy benefit included in their plan or policy.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; OOP Max = annual out-of-pocket maximum.

#### High deductible health plans

Both DMHC-regulated plans and CDI-regulated policies may be designated high deductible health plans (HDHPs).<sup>51</sup> HDHPs are a type of health plan with requirements set by federal regulation.<sup>52</sup> As the name implies, these plans include a deductible, but they are not allowed to have separate medical and pharmacy deductibles. For the 2025 plan year, the Internal Revenue Service (IRS) defines an HDHP as any plan with a deductible of at least \$1,650 for an individual and \$3,300 for a family.<sup>53</sup> Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost sharing<sup>54</sup> applicable after the deductible is met, are not allowed to be more than \$8,300 for an individual and \$16,600 for a family.<sup>55</sup>

## **Health Savings Account-qualified HDHPs**

To be eligible to establish a Health Savings Account (HSA) for taxable years beginning after December 31, 2003<sup>56</sup> (and so to be eligible to make tax-favored contributions to an HSA), a person must be enrolled in an HSA-qualified HDHP.

<sup>&</sup>lt;sup>51</sup> For enrollment estimates, see CHBRP's <u>resource</u> <u>Deductibles in State-Regulated Health Insurance</u>.

<sup>&</sup>lt;sup>52</sup> <u>HealthCare.gov, Glossary: High Deductible Health Plan (HDHP).</u> Accessed March 5, 2021.

<sup>&</sup>lt;sup>53</sup> IRS Revenue Procedure 2024-25.4.

<sup>&</sup>lt;sup>54</sup> Such as copayments and coinsurance applicable to the covered test, treatment, or service.

<sup>55</sup> There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.

<sup>&</sup>lt;sup>56</sup> Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code.



In order for an HDHP to be HSA qualified, it must follow specified rules regarding cost sharing and deductibles, as set by the IRS. Generally, an HDHP may not provide benefits for any year until the deductible for that year is satisfied, but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.<sup>57</sup> Therefore an HDHP may cover preventive care benefits without any deductible or with a deductible below the minimum annual deductible, but is not required to do so for a specified list of preventive services. The list of preventive services for which application of a deductible is not required includes treatments for chronic conditions, however it does not include HIV/AIDS.<sup>58</sup> Therefore, the requirements AB 554 would interfere with an HDHP's qualification for an HSA.

#### **Allowed Cost Amounts for Medical Services**

Insurers usually negotiate how much they will pay for the costs of covered health care services with health care providers and suppliers (Center on Budget and Policy Priorities, 2022). These negotiated amounts are known as the "allowed cost amount." Health care providers, including hospitals and physicians, participating in a plan's network agree to accept these payment amounts when an enrollee covered by the plan uses covered services. The cost-sharing charges the enrollee owes (for example, a 20% coinsurance rate) are based on this allowed cost amount. If an enrollee uses a service that is not covered or sees a provider that is not within the insurer's network, the overall charge, including an enrollee's cost sharing, could be higher than the allowed amount.

## **Utilization Management**

Utilization management techniques are used by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Examples include benefit coverage requirements related to prior authorization, step therapy, quantity limits, and limits related to the age or sex of the enrollee (such as prescription-only infant formula or prostate cancer screening for men). A brief description of some key utilization management techniques follows.

#### **Prior authorization**

Prior authorization<sup>59</sup> — also known as precertification, prior approval, or prospective review — is a utilization management technique commonly used by health insurance carriers to ensure that a given medical intervention meets the insurance plan or policy's criteria for coverage (Newcomer et al., 2017). Prior authorization developed as a tool for insurers to assess the appropriateness of treatment that would result in a hospital admission or a high-cost procedure (Resneck, 2020). The process typically requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment. Health plans/insurers may also impose prior authorization requirements on nonpreferred medications in an effort to promote the use of preferred medications that they can procure at lower prices.

The primary uses of prior authorization are as follows:

- Coverage evaluation: Allows evaluation of whether a test, treatment, or service is medically necessary and otherwise covered.
- Safety: Acts as a safeguard to confirm that a patient's medications are compatible and provides an opportunity to
  check that proper diagnostic testing has been completed to ensure patient safety prior to use of a requested
  treatment. Prior authorization also reduces inappropriate patient care by stopping unsafe or low-value care that is
  inconsistent with the most recent clinical evidence.
- Cost control: Imposition of prior authorization for nonpreferred medications can encourage the use of preferred medications that can be procured at lower price.

<sup>&</sup>lt;sup>57</sup> For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725

For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at; and Notice 2013-57, 2013-40 I.R.B. 293.

<sup>&</sup>lt;sup>58</sup> For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593 and Notice 2024-75.

<sup>&</sup>lt;sup>59</sup> More information about prior authorization is available in CHBRP's 2023 analysis *Prior Authorization in California*.



#### **Step therapy**

Step therapy or "fail-first" protocols may be applied to prescription medications by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Health plans/insurers may use step therapy protocols to apply clinical guidelines established by professional societies and other recognized organizations to treatment plans. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. Step therapy protocols usually recommend starting with a medication that is less expensive (generics) and/or has more "post-marketing safety experience" (PBMI, 2015). In addition, they sometimes require starting with a less potent medication or dosage, perhaps with fewer side effects, and graduating to more potent medications as necessary (e.g., from prescription ibuprofen to oxycodone to treat pain). Generally, more expensive or more potent medications are covered when the patient fails to respond to the step therapy–required medication (PBMI, 2018).

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# Appendix C. Cost Impact Analysis: Data Sources, Caveats, and Assumptions

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc., the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.<sup>60</sup> Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses, are available on CHBRP's website.<sup>61</sup>

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

## **Analysis-Specific Data Sources**

Current coverage of ARV drugs was assessed by a survey of the largest commercial health plans and health insurers in California. Responses to this survey represented 76.0% of DMHC-regulated commercial plans and 1.9% of CDI-regulated policies that can be subject to state benefit mandates.

CHBRP identified ARV drugs by National Drug Code (NDC) and classified the drugs according to Table 9 below. CHBRP relied upon Milliman's Consolidated Health Cost Guidelines Sources Database (CHSD) commercial California experience for this analysis.

**Table 9. ARV Drugs and Therapeutic Classes** 

Therapeutic Class	Drug
Nucleoside Reverse Transcriptase Inhibitor	Abacavir
Nucleoside Reverse Transcriptase Inhibitor	Emtricitabine
Nucleoside Reverse Transcriptase Inhibitor	Lamivudine
Nucleoside Reverse Transcriptase Inhibitor	Tenofovir disoproxil fumarate
Nucleoside Reverse Transcriptase Inhibitor	Zidovudine
NRTI Combination Products	Abacavir/lamivudine
NRTI Combination Products	Tenofovir alafenamide/emtricitabine
NRTI Combination Products	Tenofovit disoproxil fumarate/emtricitabine
NRTI Combination Products	Tenofovir disoproxil fumarate/lamuvudine
NRTI Combination Products	Zidovudine/lamivudine
NRTI Combination Products	Abacavir sulfate/zidovudine/lamivudine
Non-Nucleoside Reverse Transcriptase Inhibitor	Efavirenz
Non-Nucleoside Reverse Transcriptase Inhibitor	Doravirine
Non-Nucleoside Reverse Transcriptase Inhibitor	Etravirine

<sup>60</sup> CHBRP's <u>authorizing statute</u> requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

<sup>61</sup> See CHBRP's Cost Impact Analysis landing page; in particular, see Cost Impact Analyses: Data Sources, Caveats, and Assumptions.



Therapeutic Class	Drug
Non-Nucleoside Reverse Transcriptase Inhibitor	Nevirapine
Non-Nucleoside Reverse Transcriptase Inhibitor	Rilpivirine
Protease Inhibitor	Atazanavir
Protease Inhibitor	Atazanavir/cobicistat
Protease Inhibitor	Darunavir
Protease Inhibitor	Darunavir/cobicistat
Protease Inhibitor	Lopinavir/ritonavir
Protease Inhibitor	Tipranavir
Integrase Strand Transfer Inhibitor	Dolutegravir
Integrase Strand Transfer Inhibitor	Raltegravir
CCR5 Antagonist	Maraviroc
CD4-Directed Post-Attachment Inhibitor	Ibalizumab-uiyk
Gp120-Directed Attachment Inhibitor	Fostemasavir
Coformulated Combination Products As Single-Tablet Regiments	Bictegravir/tenofovir alafenamide/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Darunavir/cobicistat/tenofovir alafenamide/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Dolutegravir/abacavir/lamivudine
Coformulated Combination Products As Single-Tablet Regiments	Dolutegravir/lamivudine
Coformulated Combination Products As Single-Tablet Regiments	Dolutegravir/rilpivirine
Coformulated Combination Products As Single-Tablet Regiments	Doravirine/tenofovir disoproxil fumarate/lamivudine
Coformulated Combination Products As Single-Tablet Regiments	Efavirenz/tenofovir disoproxil fumarate/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Efavirenz/tenofovir disoproxil fumarate/lamivudine
Coformulated Combination Products As Single-Tablet Regiments	Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Rilpivirine/tenofovir alafenamide/emtricitabine
Coformulated Combination Products As Single-Tablet Regiments	Rilpivirine/tenofovir disoproxil fumarate/emtricitabine
Copackaged Combination Products As Injectable Regimens	Cabotegravir + rilpivirine
Pharmacokinetic Enhancers (Boosters)	Cobicistat
Pharmacokinetic Enhancers (Boosters)	Ritonavir
Copackaged Combination Products As Injectable Regimens	Lenacapavir



#### Consolidated Health Cost Guidelines Sources Database

Milliman maintains benchmarking and analytic databases that include health care claims data for nearly 60 million commercial lives and over 3 million lives of Medicaid managed care data. This dataset is routinely used to evaluate program impacts on cost and other outcomes.

## **Analysis-Specific Caveats and Assumptions**

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable. Prior CHBRP analyses of ARV bills were developed focusing on the annual cost of all ARV drugs for users of the drugs in prior calendar years, including SB 427. The methodology and results of AB 554 cost analysis are not comparable to results of prior ARV bills.

#### Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act. Individual and small-group plans and policies are subject to the mandate starting in the second year following its implementation (2027).
- AB 554 requires coverage of "antiretroviral drugs, devices, or products." No FDA-approved antiretroviral therapy drug
  devices or other products exist at this time, and CHBRP made no assumption about the coverage or utilization of such
  devices for this analysis.
- CHBRP surveyed the carriers to determine the percentage of the population with coverage for ARV drugs. For health plans and insurers who did not respond to the 2025 survey, the response from the 2023 survey for SB 427 was assumed. Commercial plans indicated coverage of ARV drugs with cost sharing varies between 89% and 100% by market segment, while coverage without cost sharing varies between 0% and 100%.
- Few survey responses were received from health insurers regulated by the CDI. CHBRP assumed that CDI-regulated
  plans have the same coverage and cost-sharing requirements as the corresponding DMHC-regulated plans in the
  same market segment.
- CHBRP assumed that CalPERS coverage and cost sharing would be equal to nongrandfathered large-group DMHC plans.

### **Methodology and Assumptions for Baseline Utilization**

- The average annual utilization for ARV drugs (by NDC code) were identified in Milliman's proprietary 2023 CHSD for commercial members in California.
- The utilization rates were trended at 0.00%.

### **Methodology and Assumptions for Baseline Cost**

- CHBRP calculated the average California commercial cost per service for ARV therapy (by NDC code) and calibrated using Milliman's proprietary 2023 CHSD.
- The average costs per service were trended at 2.85% annually.

## **Methodology and Assumptions for Baseline Cost Sharing**

CHBRP examined claims with and without cost sharing separately for this analysis. The average cost sharing
percentage for claims with cost sharing, with adjustment for the cost sharing associated with ARV drugs observed in
the CHSD data, was assumed for the baseline scenarios.



#### **Methodology and Assumptions for Postmandate Utilization**

- CHBRP assumed the utilization rate for enrollees with coverage postmandate in the first year (2026) is equal to the utilization rate for enrollees with coverage at baseline. For the second year postmandate (2027), CHBRP assumed the utilization rate for enrollees is equal to the utilization rate for enrollees with coverage at baseline plus an adjustment to account for the recent FDA application acceptance of lenacapavir for the prevention of HIV (in addition to its existing approval for the treatment of HIV), which is anticipated to be approved in June 2025. CHBRP assumed that the additional utilization would be similar to the utilization of cabotegravir in calendar year 2023.
- CHBRP assumed 100% coverage for ARV drugs postmandate.

#### **Methodology and Assumptions for Postmandate Cost**

• CHBRP assumed the average cost per service would not change as a result of AB 554.

#### Methodology and Assumptions for Postmandate Cost Sharing

• AB 554 prohibits cost sharing on ARV drugs postmandate.

#### Second-Year Impacts on Benefit Coverage, Cost, and Utilization

To develop Table 10 through Table 13, CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 554 would have a substantial impact on the utilization of ARV drugs. To generate these tables, CHBRP reviewed the literature, consulted content experts about the possibility of varied second-year impacts, and applied what was learned to a projection of a second year of implementation.

Some differences in expenditures and utilization are due to population changes between 2026 and 2027. Other differences are due to the anticipated availability of lenacapavir on the market, which CHBRP estimates would have a similar impact on utilization as other long-acting injectable ARV drugs when they were initially introduced to the market. There may also be a population who would newly consider using PrEP because of the low frequency with which one must take lenacapavir (twice a year vs. every two months for cabotegravir). Overall, CHBRP anticipates there would be an increase in the number of ARV prescriptions filled.

### Second-Year Benefit Coverage

Below, Table 10 provides estimates of how many Californians have health insurance that would have to comply with AB 554 in terms of benefit coverage during 2027.

Table 10. AB 554 Impacts on Benefit Coverage, 2027

	Baseline	Postmandate	Increase/Decrease	Percentage Change
Total enrollees with health insurance subject to state benefit mandates (a)	22,239,000	22,239,000	0	0.00%
Total enrollees with health insurance subject to AB 554	13,589,000	13,589,000	0	0.00%
Number of enrollees with partially compliant coverage for ARV drugs	233,000	0	(233,000)	-100.00%
Number of enrollees with fully compliant coverage for mandated benefit	12,944,000	13,589,000	645,000	4.98%



Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal. Key: ARV = antiretroviral; CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

Postmandate, AB 554 would result in approximately 233,000 enrollees gaining coverage for the use of ARV drugs without cost sharing out of approximately 13.6 million enrollees with outpatient prescription drug benefits in commercial plans.

### **Second-Year Utilization and Unit Cost**

Below, Table 11 provides second-year estimates of the impacts of AB 554 on utilization and unit cost of ARV drugs.

Table 11. AB 554 Impacts on Utilization and Unit Cost, 2027

	Baseline (2026)	Postmandate Year 1 (2026)	Increase/Decrease	Percentage Change
Number of enrollees using ARV drugs				
Number of enrollees using ARV drugs	95,098	96,753	1,656	1.74%
Number of enrollees using ARV drugs with cost sharing	50,893	0	-50,893	-100.00%
Number of enrollees using ARV drugs without cost sharing	59,710	96,753	37,043	62.04%
Prescriptions per user of ARV drugs with cost sharing	6.9	0	-6.9	-100.00%
Prescriptions per user of ARV drugs without cost sharing	5.1	6.9	1.8	34.76%
Percentage of enrollees using ARV drugs with cost sharing	0.4%	0.0%	-0.4%	-100.00%
Percentage of enrollees using ARV drugs without cost sharing	0.4%	0.7%	0.3%	59.26%
Utilization				
ARV drug prescriptions with cost sharing	352,122	0	-352,122	-100.00%
ARV drug prescriptions without cost sharing	307,175	670,775	363,600	118.37%
% of utilization with cost sharing	53.4%	0.0%	-53.4%	-100.00%



	Baseline (2026)	Postmandate Year 1 (2026)	Increase/Decrease	Percentage Change
% of utilization without cost sharing	46.6%	100.0%	53.4%	114.63%
Average Annual Cost (a)				
ARV drugs with cost sharing	\$19,877	\$0	-\$19,877	-100.00%
ARV drugs without cost sharing	\$8,689	\$16,093	\$7,404	85.22%
Average annual cost sharing (a)				
ARV drugs with cost sharing	\$1,943	\$0	-\$1,943	-100.00%
ARV drugs without cost sharing	\$0	\$0	\$0	0.00%

Notes: Estimates related to prescriptions are for prescriptions filled, which is inclusive of first fills and refills for the year.

(a) Average annual cost and average annual cost sharing refer to the annual cost of an ARV regimen. Additional treatments and potential costs of complications or side effects are not included.

Key: ARV = antiretroviral.

## **Second-Year Expenditures**

Table 12 provides second-year estimates of the impacts of AB 554 on expenditures, which include premiums, enrollee cost sharing, and enrollee expenses for noncovered benefits. For DMHC-regulated plans and CDI-regulated policies, AB 554 would increase total premiums paid by employers and enrollees for newly covered benefits. Enrollee expenses for covered and/or noncovered benefits would decrease. Overall, second-year expenditures would be anticipated to be higher than first-year expenditures.

Table 12. AB 554 Impacts on Expenditures, 2027

	Baseline Year 2 (2027)	Postmandate Year 2 (2027)	Increase/Decrease	Percentage Change
Premiums				
Employer-sponsored (a)	\$73,833,306,000	\$73,907,499,000	\$74,193,000	0.10%
CalPERS employer (b)	\$8,522,707,000	\$8,528,888,000	\$6,181,000	0.07%
Medi-Cal (excludes COHS) (c)	\$32,904,356,000	\$32,904,356,000	\$0	0.00%
Enrollee premiums				
Enrollees, individually purchased insurance	\$23,617,760,000	\$23,649,600,000	\$31,840,000	0.13%
Outside Covered California	\$6,530,812,000	\$6,541,366,000	\$10,554,000	0.16%



	Baseline Year 2 (2027)	Postmandate Year 2 (2027)	Increase/Decrease	Percentage Change
Through Covered California	\$17,086,948,000	\$17,108,234,000	\$21,286,000	0.12%
Enrollees, group insurance (d)	\$23,328,885,000	\$23,352,659,000	\$23,774,000	0.10%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copays, etc.)	\$20,485,892,000	\$20,386,991,000	-\$98,901,000	-0.48%
Expenses for noncovered benefits (e)	\$0	\$0	\$0	0.00%
Total expenditures	\$182,692,906,000	\$182,729,993,000	\$37,087,000	0.02%

Notes: (a) In some cases, a union or other organization. Excludes CalPERS.

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

Table 13. Impact of AB 554 on Average Enrollee Out-of-Pocket Expenses, 2027

	Large Group	Small Group	Individual	CalPERS	Medi-Cal (b)
Enrollees with baseline benefit coverage	8,115,212	2,146,000	2,198,995	896,271	0
% of enrollees with out-of-pocket expenses impact due to AB 554 (a)	0.38%	0.38%	0.38%	0.38%	N/A
Avg. annual out-of-pocket expenses impact for enrollees	(\$1,307)	(\$2,932)	(\$3,579)	(\$1,325)	N/A
Enrollees with new benefit coverage	203,788	0	9,005	19,729	0
% of enrollees with out-of-pocket expenses impact due to AB 554 (a)	0.00%	0.00%	0.00%	0.00%	N/A
Avg. annual out-of-pocket expenses impact for enrollees	\$0.00	\$0.00	\$0.00	\$0.00	N/A

#### Source: California Health Benefits Review Program, 2025.

Notes: Average enrollee out-of-pocket expenses include cost sharing (e.g., deductibles, copayments, and coinsurance) and out-of-pocket expenses for noncovered benefits.

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<sup>(</sup>b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.<sup>62</sup> CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

<sup>(</sup>d) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

<sup>(</sup>e) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

<sup>(</sup>a) Not including impacts on premiums.

<sup>(</sup>b) Benefit coverage for Medi-Cal beneficiaries is not subject to AB 554.

Key: CalPERS = California Public Employees' Retirement System.

<sup>62</sup> For more detail, see CHBRP's resource Pharmacy Benefit Coverage in State-Regulated Health Insurance.



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## **About CHBRP**

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP Faculty Task Force comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are Task Force Contributors to CHBRP from UC that conduct much of the analysis. The CHBRP staff works with Task Force members in preparing parts of the analysis, and manages external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with an independent actuarial firm, Milliman, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. The National Advisory Council provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. Information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at <a href="https://chbrp.org">chbrp.org</a>.

#### CHBRP Staff

Garen Corbett, MS, Director
Adara Citron, MPH, Associate Director
An-Chi Tsou, PhD, Principal Policy Analyst
Anna Pickrell, MPH, Principal Policy Analyst
Karen Shore, PhD, Contractor\*
Nisha Kurani, MPP, Contractor\*
\*Independent Contractor working with CHBRP to support analyses and other projects.

Faculty Task Force

Paul Brown, PhD, University of California, Merced
 Timothy T. Brown, PhD, University of California, Berkeley
 Shana Charles, PhD, MPP, University of California, Los Angeles, and
 California State University, Fullerton

Janet Coffman, MA, MPP, PhD, Vice Chair for Medical Effectiveness, University of California, San Francisco

Todd Gilmer, PhD, University of California, San Diego Sylvia Guendelman, PhD, LCSW, University of California, Berkeley Elizabeth Magnan, MD, PhD, Vice Chair for Medical Effectiveness

and Public Health, University of California, Davis

Sara McMenamin, PhD, Vice Chair for Medical Effectiveness and Public Health, University of California, San Diego
Joy Melnikow, MD, MPH, University of California, Davis

Aimee Moulin, MD, University of California, Davis

Jack Needleman, PhD, University of California, Los Angeles Mark A. Peterson, PhD, University of California, Los Angeles

Nadereh Pourat, PhD, Vice Chair for Cost, University of California,

Dylan Roby, PhD, University of California, Irvine
Marilyn Stebbins, PharmD, University of California, San Francisco
Jonathan Watanabe, PharmD, MS, PhD, University of California, San
Francisco

#### Task Force Contributors

Bethney Bonilla-Herrera, MA, University of California, Davis
Danielle Casteel, MA, University of California, San Diego
Margaret Fix, MPH, University of California, San Francisco
Carlos Gould, PhD, University of California, San Diego
Julia Huerta, BSN, RN, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles, and
University of Southern California

Xenia Mendez, MPH, University of California, San Francisco Thet Nwe Myo Khin, MPH, University of California, San Diego Jacqueline Miller, University of California, San Francisco Marykate Miller, MS, University of California, Davis Katrine Padilla, MPP, University of California, Davis Kyoko Peterson, MPH, University of California, San Francisco Amy Quan, MPH, University of California, San Francisco Dominique Ritley, MPH, University of California, Davis Riti Shimkhada, PhD, University of California, Los Angeles Meghan Soulsby Weyrich, MPH, University of California, Davis Steven Tally, PhD, University of California, San Diego

#### National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, *Chair* Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA

**Deborah Chollet, PhD,** Senior Fellow, Mathematica Policy Research, Washington, DC

**Allen D. Feezor,** Former Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC

**Charles "Chip" Kahn, MPH,** President and CEO, Federation of American Hospitals, Washington, DC

Jeffrey Lerner, PhD, President Emeritus, ECRI Institute Headquarters, Plymouth Meeting, PA; Adjunct Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania

Donald E. Metz, Executive Editor, Health Affairs, Washington, DC Dolores Mitchell, (Retired) Executive Director, Group Insurance Commission, Boston, MA

**Marilyn Moon, PhD,** (Retired) Senior Fellow, American Institutes for Research, Washington, DC

Rachel Nuzman, MPH, Senior Vice President for Federal and State Health Policy, The Commonwealth Fund, New York, NY

Carolyn Pare, (Retired) President and CEO, Minnesota Health Action Group, Bloomington, MN

Osula Evadne Rushing, MPH, Senior Vice President for Strategic Engagement, KFF, Washington, DC

Ruchika Talwar, MD, MMHC, Assistant Professor Department of Urology and Medical Director Episodes of Care, Population Health, Vanderbilt University Medical Center

Alan Weil, JD, MPP, Senior Vice President for Public Policy, AARP, Washington, DC

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Katie Matthews, FSA, MAAA, of Milliman provided actuarial analysis. Jennifer Cocohoba, PharmD, of the University of California, San Francisco, provided technical assistance with the literature search and expert input on the analytic approach. An-Chi Tsou, PhD, of CHBRP staff prepared the abbreviated analysis. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and members of the CHBRP Faculty Task Force, Todd Gilmer, PhD, of the University of California, San Diego; and Marilyn Stebbins, PharmD, of the University of California, San Francisco, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at <a href="https://chbrp.org">chbrp.org</a>.

Garen Corbett, MS Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or <a href="mailto:chbrp.org">chbrp.org</a>, or <a

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