

California Health Benefits Review Program

Analysis of California Senate Bill 427 Antiretroviral Drugs, Devices, and Products

A Report to the 2023–2024 California State Legislature

April 21, 2023



Key Findings

Analysis of California Senate Bill 427

Antiretroviral Drugs, Devices, and Products

Summary to the 2023–2024 California State Legislature, April 21, 2023



AT A GLANCE

The version of California Senate Bill 427 analyzed by CHBRP would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover all U.S. Food and Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended antiretroviral drugs, products, and devices (ARVs) for HIV/AIDS with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

In 2024, 100% of the 22.8 million Californians enrolled in state-regulated health insurance would have insurance subject to SB 427.

Benefit Coverage: At baseline, 98.9% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for ARVs, while only 38.6% of enrollees have coverage fully compliant with SB 427. Postmandate, 100% of enrollees with coverage subject to SB 427 would have coverage with ARVs without cost sharing. SB 427 would not be likely to exceed essential health benefits (EHBs).

Medical Effectiveness: CHBRP researched the effects of cost sharing and utilization management on ARV use and adherence for patients with HIV and those at risk of contracting HIV. CHBRP found:

- *Inconclusive evidence* on the effect of cost sharing for ARVs on long-term adherence and viral suppression for people living with HIV.
- *Insufficient evidence* on the effect of cost sharing for ARVs on health care utilization and health outcomes.
- *Insufficient evidence* on the effect of utilization management for ARVs on health care utilization and health outcomes.

Cost and Health Impacts¹: In 2024, CHBRP estimates SB 427 would increase total net annual expenditures by \$51,601,000 or 0.0352% for enrollees with DMHC-regulated health plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal. This is due to a \$157,254,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$105,653,000 decrease in enrollee expenses for covered and/or noncovered benefits.

SB 427 would result in an increase of 1,402 enrollees utilizing ARVs for a total utilization equal to 132,133 enrollees. This includes an increase in the number of individuals who do not seroconvert due to pre-exposure prophylaxis (47) and postexposure prophylaxis (22) access, an increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (1,332), and a subsequent decrease in both short- and long-term adverse health outcomes (including a reduction in the transmission of HIV to noninfected sexual partners).

The impacts of SB 427 on disparities are unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARV utilization among newly covered enrollees.

CONTEXT

Human immunodeficiency virus (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.² Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection; (2) chronic HIV infection; and (3) acquired immunodeficiency syndrome (AIDS). 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 antiretroviral therapy—known for inhibiting viral replication and allowing for immune reconstitution. Given the availability of ARVs, it is possible for people living

¹ 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.

² Refer to CHBRP's full report for citations and references.

with HIV to achieve a life expectancy similar to that of the general population.

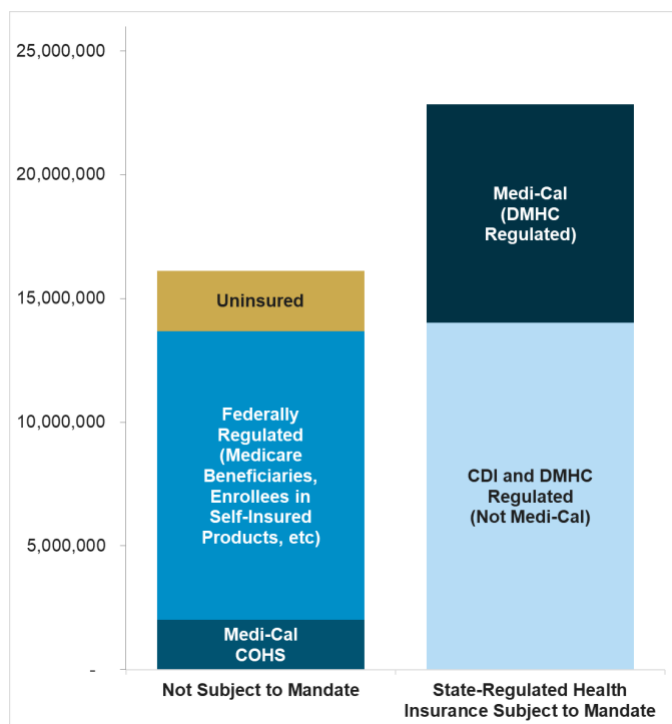
The U.S. Department of Health and Human Services recommends that the primary goal of ARVs is to prevent HIV-associated morbidity and mortality and to reduce the risk of HIV transmission to sexual partners and to infants born to persons with HIV. ARVs are widely accepted as effective treatment for the control of HIV as well as the prevention of transmission of HIV.

BILL SUMMARY

SB 427 would require Department of Managed Health Care (DMHC)-regulated health plans and California Department of Insurance (CDI)-regulated policies to cover all U.S. Food and Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended ARVs with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

Figure A notes how many Californians have health insurance that would be subject to SB 427.

Figure A. Health Insurance in CA and SB 427



Source: California Health Benefits Review Program, 2023.

Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, 100% (22,842,000) of enrollees with DMHC- or CDI-regulated health insurance plans/policies would have coverage subject to SB 427. Of these, 98.9% have coverage for ARVs. At baseline, 38.6% of enrollees have coverage for ARVs that is fully compliant with SB 427. Postmandate, 100% of enrollees with coverage subject to SB 427 would have coverage for ARVs without cost sharing.

Although the benefit coverage for beneficiaries with DMHC-regulated Medi-Cal plans is subject to SB 427, their pharmacy benefit is carved out and administered under Medi-Cal Rx, and therefore, SB 427 would not impact their benefit coverage.

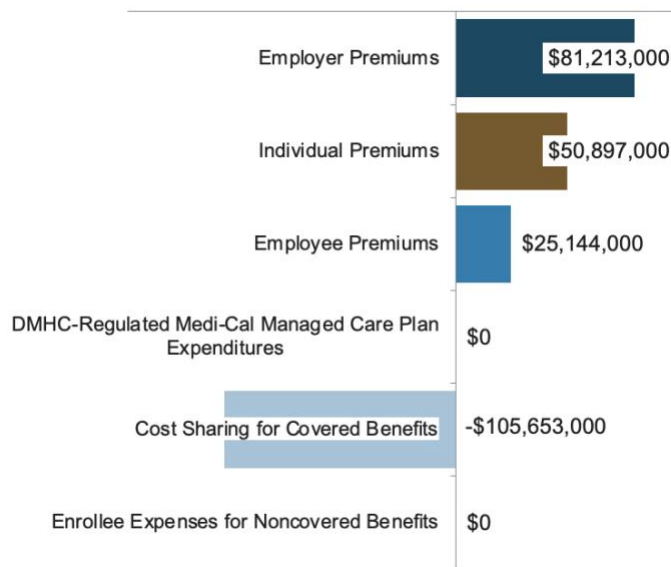
Utilization

At baseline, CHBRP estimates that 130,731 enrollees per year in DMHC-regulated plans and CDI-regulated policies used ARVs with cost sharing. Among these, 49,257 enrollees per year used ARVs with cost sharing and 97,658 enrollees used ARVs with no cost sharing. It is important to note that these two groups had some overlap (16,184 enrollees), as some enrollees had cost sharing during the year until hitting their maximum out-of-pocket limit, and then had no cost sharing for the remainder of the year. On average, each enrollee with cost sharing had on average 7.6 prescriptions annually with cost sharing at baseline, with an average of 6.5 prescriptions for enrollees with no cost sharing.

Postmandate, CHBRP estimates an additional 1,402 enrollees will utilize ARVs (equal to 132,133 enrollees overall), representing a 1% increase in enrollees using ARVs overall. On average, enrollees who use ARVs would obtain 7.7 prescriptions without cost sharing annually, per person. This translates to an overall utilization of 1,016,959 ARV prescriptions without cost sharing, postmandate, representing a 1% increase in ARV prescriptions.

Expenditures

SB 427 would increase total net annual expenditures by \$51,601,000 or 0.0352% for enrollees with DMHC-regulated plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal.

Figure B. Expenditure Impacts of SB 427

Source: California Health Benefits Review Program, 2023.

Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.

CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, premiums would increase by 0.08% (\$0.53 per member per month, or approximately \$4.7 million total increase in expenditures).

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 SB 427.

Medical Effectiveness

CHBRP reviewed findings from evidence on the effects of cost sharing and utilization management on ARVs (including pre-exposure prophylaxis [PrEP] and postexposure prophylaxis [PEP]) use and adherence for patients with HIV and those at risk of contracting HIV.

³ *Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

CHBRP did not review literature on the effectiveness of ARVs because all ARVs have been approved by the FDA, and the efficacy of ARVs is well-established.

CHBRP found:

- *Inconclusive evidence*³ on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.
- *Insufficient evidence*⁴ on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes.
- *Insufficient evidence* on the effect of utilization management for ARVs (including PrEP and PEP) health care utilization and health outcomes.

Public Health

Measurable health outcomes relevant to SB 427 include adherence to prescribed ARVs regimens and viral suppression, health care utilization, and HIV-related complications or comorbidities.

In the first year postmandate, CHBRP estimates an additional 1,402 enrollees would seek ARVs overall for the prevention or treatment for HIV/AIDS. This includes an increase in the number of individuals who do not seroconvert due to PrEP (47) and PEP (22) access, an increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (1,332), and a subsequent decrease in both short- and long-term adverse health outcomes (including a reduction in the transmission of HIV to noninfected sexual partners).

The impacts of SB 427 on disparities related to race or ethnicity, gender, gender identity or sexual orientation, and age are unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARVs utilization among newly covered enrollees.

Long-Term Impacts

The utilization increases estimated in this report are not expected to be different over the long-term. However, over time, adherence to ARVs may improve as cost sharing will no longer be a barrier, which could lead to an increase in overall annual utilization. However, this

⁴ *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

effect would be limited because adherence is also dependent on other factors, such as the severity of side effects and access to health care.

Cost impacts over the long term would be proportional to any increase in utilization and are not anticipated to change after the first year postmandate. Although additional use of and adherence to ARVs will prevent HIV infection and later AIDS-related diseases, the marginal impact of SB 427 over the existing use of ARVs cannot be quantified. Additionally, the vast array of AIDS-related diseases that could occur and would be prevented cannot be quantified; in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to SB 427.

The long-term public health impacts of SB 427 are likely to include a reduction in future HIV transmissions (i.e., reduction in HIV incidence among those using PrEP and PEP), increased uptake of and adherence to ARVs (leading to a subsequent reduction in the number of overall adverse health outcomes in the long-term), as well as a reduction in downstream effects such as impacts on premature death.

Essential Health Benefits and the Affordable Care Act

SB 427 does not exceed essential health benefits because the bill would specify terms and conditions of coverage for ARVs and not mandate coverage for new tests, treatments, or services for nongrandfathered health plans or policies.

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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.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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Table 1. Impacts of SB 427 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline (2024)	Postmandate Year 1 (2024)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,842,000	22,842,000	0	0.00%
Total enrollees with health insurance subject to SB427	22,842,000	22,842,000	0	0.00%
Number of enrollees with coverage for ARVs	22,599,704	22,842,000	242,296	1.07%
Number of enrollees with fully compliant coverage for ARVs	8,817,000	22,842,000	14,025,000	159.07%
Utilization and cost				
Number of enrollees using ARVs				
Number of enrollees using ARVs	130,731	132,133	1,402	1.07%
Number of enrollees using ARVs with cost sharing	49,257	—	-49,257	-100.00%
Number of enrollees using ARVs without cost sharing	97,658	132,133	34,475	35.30%
Prescriptions per user of ARVs with cost sharing	7.6	—	-7.6	-100.00%
Prescriptions per user of ARVs without cost sharing	6.5	7.7	1.2	18.58%
Percentage of enrollees using ARVs with cost sharing	0.2%	0.0%	-0.2%	-100.00%
Percentage of enrollees using ARVs without cost sharing	0.4%	0.6%	0.1%	33.87%
Utilization				
ARVs with cost sharing	372,340	—	-372,340	-100.00%
ARVs without cost sharing	633,832	1,016,959	383,127	60.45%
% of utilization with cost sharing	37.0%	0.0%	-37.0%	-100.00%
% of utilization without cost sharing	63.0%	100.0%	37.0%	58.74%
Average annual cost per enrollee using ARVs (b)				
ARVs with cost sharing	\$19,684	\$0	-\$19,684	-100.00%
ARVs without cost sharing	\$10,280	\$15,116	\$4,836	47.04%
Average annual cost sharing per enrollee using ARVs (b)				
ARVs with cost sharing	\$2,145	\$0	-\$2,145	-100.00%
ARVs without cost sharing	\$0	\$0	\$0	0.00%
Expenditures				
<u>Premiums</u>				
Employer-sponsored (c)	\$57,647,993,000	\$57,724,542,000	\$76,549,000	0.1328%
CalPERS employer (d)	\$6,158,262,000	\$6,162,926,000	\$4,664,000	0.0757%
Medi-Cal (excludes COHS) (e)	\$29,618,383,000	\$29,618,383,000	\$0	0.0000%
<u>Enrollee premiums (expenditures)</u>				
Enrollees, individually purchased insurance	\$21,229,233,000	\$21,280,130,000	\$50,897,000	0.2397%
Outside Covered California	\$4,867,955,000	\$4,882,317,000	\$14,362,000	0.2950%

Through Covered California	\$16,361,278,000	\$16,397,813,000	\$36,535,000	0.2233%
Enrollees, group insurance (f)	\$18,263,775,000	\$18,288,919,000	\$25,144,000	0.1377%
<i>Enrollee out-of-pocket expenses</i>				
Cost sharing for covered benefits (deductibles, copayments, etc.)	\$13,857,141,000	\$13,751,488,000	-\$105,653,000	-0.7624%
Expenses for noncovered benefits (g) (h)	\$0	\$0	\$0	0.0000%
Total expenditures	\$146,774,787,000	\$146,826,388,000	\$51,601,000	0.0352%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁵

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

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

(d) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁶ 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).

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

(f) 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.

(g) 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 will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(h) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).

Key: ARVs = antiretroviral drugs, devices, and products; CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

⁵ For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

⁶ For more detail, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁷ conduct an evidence-based assessment of the medical, financial, and public health impacts of SB 427, Antiretroviral Drugs, Devices, and Products, as amended on March 21, 2023.

Bill-Specific Analysis of SB 427, Antiretroviral Drugs, Devices, and Products

Bill Language

SB 427 would mandate coverage for, and certain cost sharing and utilization management terms on the coverage of, all antiretroviral drugs, devices, and products either approved by the U.S. Food & Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC).

Specifically, SB 427 would include the following mandates regarding FDA-approved or CDC-recommended antiretroviral drugs, devices, and products (ARVs):

- For nongrandfathered and grandfathered health plans regulated by the Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI):
 - Prohibition on cost sharing.
 - Prohibition on utilization review requirements, including step therapy or prior authorization, unless the health plan or policy does both the following:
 - Covers at least one therapeutic equivalent without prior authorization or step therapy; and
 - Provides coverage for a noncovered therapeutic equivalent ARV without cost sharing through an exception request.
- For grandfathered DMHC-regulated plans and CDI-regulated policies, mandate for coverage.
- Requires coverage under the outpatient prescription drug benefit, regardless of whether the drugs are self-administered.

The full text of SB 427 can be found in Appendix A.

Relevant Populations

If enacted, SB 427 would apply to the health insurance of approximately 22.8 million enrollees (58.6% of all Californians) in DMHC-regulated plans and CDI-regulated policies. This represents all Californians who have health insurance regulated by the state that may be subject to any state health benefit mandate law.⁸ However, as of January 1, 2022, outpatient prescription drugs are covered on a fee-for-service basis for all Medi-Cal beneficiaries under the California Department of Health Care Services (DHCS)'s Medi-Cal Rx program.⁹ Their pharmacy benefit is "carved out" of the coverage provided by Medi-Cal managed care plans, and therefore SB 427 would not impact their benefit coverage.

⁷ CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

⁸ Health insurance subject to a state health benefit mandate law includes all health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI).

⁹ For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

Analytic Approach and Key Assumptions

CHBRP previously analyzed similar bill language, SB 159 in 2019, and has also been asked to analyze SB 339 of 2023. Where applicable, this analysis builds off those two.

CHBRP uses the term ARVs throughout the analysis to include all antiretroviral drugs, devices, and products. As of the publishing of this report, there are no FDA-approved or CDC-recommended antiretroviral devices or products; thus CHBRP's analysis focuses only on antiretroviral drugs.

Based on the language of SB 427, CHBRP has assumed that the drug cabotegravir, an injectable antiretroviral medication used for HIV pre-exposure prevention, will be offered on the pharmacy benefit. As SB 427 is only concerned with coverage for ARVs and not administration of the drug, device, or product, CHBRP's analysis focuses solely on the impact to the pharmacy benefit. It should be noted that not all DMHC-regulated plans and CDI-regulated policies include a pharmacy benefit.¹⁰ Because SB 427 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 compliant.

Interaction With Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

Existing law prohibits step therapy and prior authorization of medically necessary antiretroviral drugs for the prevention of AIDS/HIV.¹¹ Note that existing law does not require the antiretroviral drugs to be FDA-approved or CDC-recommended.

California has also introduced SB 339, which would require, among other things, DMHC-regulated health plans and CDI-regulated policies to reimburse for all pharmacist services and testing related to the furnishing of pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP). Some of the provisions of SB 339 and SB 427 modify the same code sections of law.

Similar requirements in other states

New Jersey, New York, and Oregon have also introduced legislation relating to coverage of antiretroviral drugs and associated terms and conditions. New Jersey's legislation would require coverage for certain drug regimens, including those in the form of a single tablet if proven to be as effective as a multitablet regimen.¹² New York's would prohibit restrictions or delays in the distribution of antiretroviral prescription drugs.¹³ The Oregon bill would, among other things, prohibit cost sharing for HIV postexposure prophylactic drugs or therapies following an enrollee's possible exposure to HIV.¹⁴

¹⁰ See CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: <https://www.chbrp.org/other-publications/resources>.

¹¹ Health and Safety Code (HSC) 1342.74; Insurance Code (INS) 10123.1933.

¹² New Jersey SB 1125 and AB 4504.

¹³ New York SB 1001 and Assembly Bill (AB) 1619.

¹⁴ Oregon House Bill 2574.

California Patient Assistance Programs

The California Department of Public Health (CDPH)'s Office of AIDS administers the PrEP Assistance Program (PrEP-AP) to increase accessibility to, and uptake of, PrEP for eligible Californians. Fully enrolled PrEP-AP clients have access to several services at no cost, including:

- ARVs (including PrEP and PEP);
- Medications for the treatment and prevention of sexually transmitted infections (STIs);
- Testing for HIV, STIs, 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 Line (FPL), 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 (ADAP) 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 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% FPL based on household size and income, and not being fully covered by Medi-Cal or any other third-party payers.

Preventive services

Existing California law requires coverage of the following preventive services without cost sharing or prior authorization:¹⁵

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
 - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
 - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).

These requirements align with the federal preventive services listed under the Affordable Care Act.¹⁶

The USPSTF currently recommends that clinicians offer PrEP with effective ARVs to those who are at high risk of acquiring HIV (Grade A).¹⁷ Therefore, PrEP, one of several ARVs, must be covered without

¹⁵ HSC 1367.002; INS 10112.2.

¹⁶ As of the published date of this report, the federal preventive services mandate was being challenged in court in *Braidwood Management Inc v. Becerra*. A federal judge ruled that the ACA's requirement to cover HIV prevention drugs violated religious freedom. However, 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.

¹⁷ As of the published date of this report, this topic is being updated by the USPSTF. The draft recommendation is consistent with the current one.

cost sharing when delivered by in-network providers under all nongrandfathered group and individual health insurance plans and policies.

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 SB 427 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).^{18,19}

Essential Health Benefits

In California, nongrandfathered²⁰ individual and small-group health insurance is generally required to cover essential health benefits (EHBs).²¹ In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.²²

States may require state-regulated health insurance to offer benefits that exceed EHBs.^{23,24,25} 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.²⁶

SB 427 does not exceed EHBs because the bill would specify terms and conditions of coverage for ARVs.

¹⁸ 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:

www.chbrp.org/other_publications/index.php.

¹⁹ 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.

²⁰ 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.” Available at: www.healthcare.gov/glossary/grandfathered-health-plan.

²¹ For more detail, see CHBRP's issue brief, *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at: http://www.chbrp.org/other_publications/index.php.

²² See CHBRP's resource, *Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, both available at: http://www.chbrp.org/other_publications/index.php.

²³ ACA Section 1311(d)(3).

²⁴ 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. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

²⁵ However, as laid out in the Final Rule on EHBs the 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 state-mandated 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.

²⁶ 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. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

Cost Sharing and Utilization Management

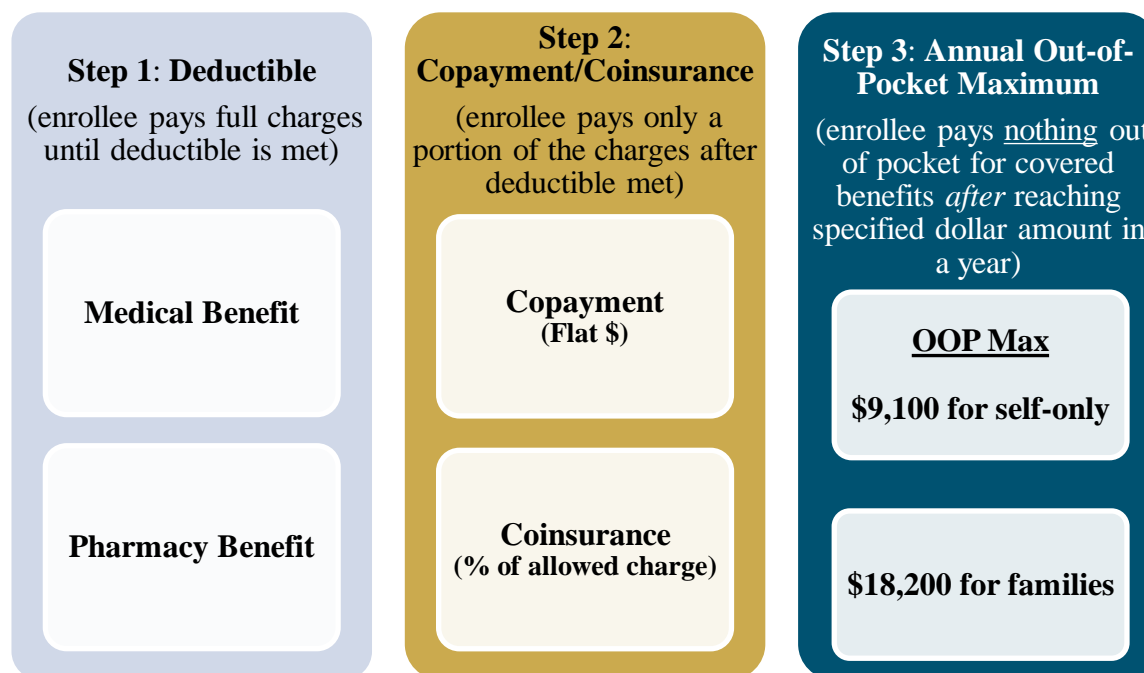
This section provides an overview of the cost-sharing and utilization management structures used for health insurance benefits, including prescription drugs.

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 expenses²⁷). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 1). 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.²⁸

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.

Figure 1. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2023; CMS, 2022.

Note: 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

²⁷ 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 the Covered California, or they receive benefits through Medi-Cal.

²⁸ 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 within the required actuarial value limits.

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, 2022).

Key: OOP Max = annual out-of-pocket maximum.

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 – 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. SB 427 would prohibit prior authorization for all FDA-approved and CDC-recommended ARVs.

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 and 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). SB 427 would prohibit step therapy for all FDA-approved and CDC-recommended ARVs.

BACKGROUND ON ANTIRETROVIRALS FOR THE PREVENTION AND TREATMENT OF HIV/AIDS

As noted in the *Policy Context*, SB 427 would require health plans / health insurers to provide coverage for U.S. Food and Drug Administration (FDA)-approved antiretroviral drugs (or drugs recommended by the Centers for Disease Control and Prevention [CDC]), devices, or products (also known as ARVs). Health plans would not need to cover all therapeutically equivalent versions without prior authorization or step therapy (i.e., utilization management techniques) if they provide coverage for a noncovered therapeutic equivalent ARVs drug/device/product without cost sharing. For nongrandfathered and grandfathered plans, SB 427 prohibits cost sharing and utilization management for FDA-approved or CDC-recommended ARVs drugs, devices, or products. This background section provides information related to antiretrovirals for the prevention and treatment of HIV/AIDS (i.e., ARVs) for the consideration of the medical effectiveness, cost and utilization, and public health impacts.

Human Immunodeficiency Virus

Human immunodeficiency virus (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. HIV spreads via direct contact with certain bodily fluids of an individual with a detectable viral load. 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 infection²⁹; (2) chronic HIV infection³⁰; and (3) acquired immunodeficiency syndrome (AIDS)³¹ (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 antiretroviral therapy³² (ARVs) – known for inhibiting viral replication and allowing for immune reconstitution (CDC, 2023). Given the availability of ARVs, 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).

Antiretrovirals for Prevention of HIV/AIDS

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. PrEP and PEP are an essential part of the HIV prevention toolbox, which also includes education, needle exchanges, and condom programs. Both strategies involve using antiretroviral therapy (ARVs) 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.

²⁹ 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).

³⁰ 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).

³¹ 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).

³² Antiretroviral therapy (ARVs) refers to treatment with highly effective antiretroviral drugs to suppress HIV replication. ARVs is comprised of more than 30 antiretroviral drugs from eight FDA-approved HIV drug classes that may be used to prevent HIV infection (i.e., PrEP or PEP) or treat HIV infection (DHHS, 2022).

PrEP

PrEP is a long-term regimen³³ 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 (F/TDF, F/TAF), and one FDA-approved injection for use as PrEP (CAB-LA) (see Table 2) (CDC, 2022b).

Oral PrEP medications

Two oral medications have been approved by the FDA for PrEP use. For both medications, PrEP users are instructed to take a single tablet once per day as long as they remain in circumstances where HIV exposure is likely to occur (CDC/USPHS, 2021). FDA-approved in 2012, emtricitabine and tenofovir disoproxil fumarate (F/TDF), the generic medication equivalent to Truvada, is the most commonly prescribed medication for PrEP, including among women and persons who inject drugs (PWID) on medication-assisted therapy (CDC/USPHS, 2021). Emtricitabine and tenofovir alafenamide (F/TAF) (i.e., Descovy) was approved by the FDA in 2019 for daily PrEP use by men and transgender women at sexual risk (CDC/USPHS, 2021). It's important to note that F/TAF is not recommended for people assigned female sex at birth who could get HIV through receptive vaginal intercourse (CDC/USPHS, 2021).

Cabotegravir PrEP injection medication

In December 2021, long-acting cabotegravir (also known as CAB-LA) was approved by the FDA for PrEP use via intramuscular injection, currently available as Apretude (FDA, 2021). Unlike oral PrEP medications which require daily adherence, 600 mg of CAB-LA can be injected in the gluteal muscle every two months for individuals at high risk for HIV (CDC/USPHS, 2021). An optional 30 mg of daily oral CAB may also be taken for a 4-week lead-in prior to injections among individuals who may be concerned about potential side effects associated with CAB-LA. Per the CDC, CAB-LA may be preferred among patients at high risk for HIV who may also be experiencing issues with adherence to a daily PrEP dosing schedule and/or experiencing serious kidney disease (CDC/USPHS, 2021).

Table 2. PrEP Medications

Generic Medication	Brand Name	Common Dosage	Frequency	Potential Side Effects
F/TDF	Truvada	200 mg/300 mg 167 mg/250 mg	Once per day	Rash, headache, nausea, abdominal pain, weight loss, loss of bone mineral density (a)
F/TAF	Descovy	200 mg/25 mg 120mg/15mg	Once per day	Diarrhea, nausea, headache, fatigue, stomach discomfort, weight gain, loss of

³³ 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).

				bone mineral density (a)
CAB-LA	Apretude	600 mg	Intramuscular injection every 2 months (b)	Pain, tenderness, and skin induration at the injection site

Source: CHBRP, 2023 based on CDC/USPHS, 2021.

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) CAB-LA is administered via injection into the gluteal muscle.

Key: F/TDF = tenofovir disoproxil fumarate; F/TAF = emtricitabine and tenofovir alafenamide, mg = milligrams; PrEP = pre-exposure prophylaxis.

PEP

PEP is a short-term, daily therapy similar to PrEP. 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/USPHS, 2016). In combination with the single tablet, F/TDF, adult patients also take another drug such as raltegravir (twice) or dolutegravir (once) daily. 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), men who have sex with men (MSM), PWID, as well as for the prevention of perinatal HIV transmission.³⁴

Antiretrovirals to Treat HIV/AIDS

ARVs refer to treatment with highly effective antiretroviral drugs³⁵ to suppress HIV replication.³⁶ Per the Panel on Antiretroviral Guidelines for Adults and Adolescents (PAGAA), ARVs are recommended for all individuals with HIV, regardless of CD4 cell count, to reduce HIV-related morbidity and mortality during all stages of infection (DHHS, 2022). The goal of ARVs is to provide a strong yet safe and tolerable (and easy-to-adhere-to) regimen for those with HIV to achieve sustained viral suppression. Current treatment guidelines recommend initiation of an HIV treatment regimen generally comprised of two nucleoside reverse transcriptase inhibitors (NRTI) administered in combination with a third drug from one of three drug classes:

1. An integrase strand transfer inhibitor (INSTI);
2. A non-nucleoside reverse transcriptase inhibitor (NNRTI); or
3. A protease inhibitor (PI) with a pharmacokinetic enhancer (also known as a booster) as soon as possible post-diagnosis (DHHS, 2022).

Additionally, the PAGAA endorses the use of a two-drug regimen, dolutegravir (DTG) plus lamivudine (3TC), for ARVs initiation (DHHS, 2022). Additional details regarding recommended initial ARV regimens can be found in the PAGAA (DHHS, 2022).

³⁴ It's important to note that the prevention of perinatal HIV transmission is composed of three components: (1) fully suppressive ARVs among pregnant persons throughout pregnancy; (2) intrapartum ARVs (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).

³⁵ SB 427 defines ARVs as any FDA-approved (or CDC-recommended) drugs, products, or devices. To date, CHBRP is unaware of any FDA-approved or CDC-recommended ARVs products or devices.

³⁶ ARVs is comprised of more than 30 antiretroviral drugs from eight FDA-approved HIV drug classes (DHHS, 2022). To view a complete list of the eight FDA-approved HIV drug classes, refer to Appendix B.

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 U.S.* initiative). California witnessed declines in both the annual number and rate of new HIV diagnoses over a 4-year period. From 2016 to 2020, the number of new HIV diagnoses declined by approximately 23% – from 5,140 in 2016 to 3,965 in 2020 (CDPH, 2022a). Similarly, the rate of new diagnoses per 100,000 population declined by approximately 24%, from 13.1 to 9.9 during the same period (CDPH, 2022a). During the same 4-year period (2016 to 2020), the number of persons living with HIV increased in California – from approximately 133,000 to more than 139,000 – indicating the effectiveness of initiating and sustaining ARV use (CDPH, 2022a).

Table 3 identifies prevalence and incidence of HIV in California by select demographic characteristics (i.e., age, race/ethnicity, and gender) in 2020.

Table 3. Prevalence and Incidence of HIV by Select Demographic Characteristics in California, 2020

Demographic Characteristic	Prevalence N (Rate)	Incidence N (Rate)
Age, years		
18-24	2,633 (96.5)	623 (24.3)
25-34	19,400 (716.8)	1,562 (57.2)
35-44	26,034 (988.3)	831 (31.3)
45-54	34,181 (1,379.9)	530 (21.4)
55 and older	57,187 (2,122.1)	371 (14.2)
Race/ethnicity		
American Indian/Alaska Native	342 (165.9)	11 (5.3)
Asian	5987 (96.7)	216 (3.5)
Black/African American	23,643 (987.7)	688 (28.7)
Latino	53824 (344.5)	1,987 (12.7)
Multiple races/unknown races	4898 (551.9)	96 (10.8)
Native Hawaiian/other Pacific Islander	263 (193.8)	12 (8.8)
White	50,746 (345.4)	955 (6.5)
Gender		
Alternative gender identity	9 (–)*	2 (–)*

Cisgender men	121,054 (607.0)	3,358 (16.8)
Cisgender women	16,402 (81.2)	490 (2.4)
Transgender men	78 (–)*	4 (–)*
Transgender women	2,160 (–)*	111 (–)*
Total	139,703 (348.1)	3,965 (9.9)

Source: California Health Benefits Review Program, 2023, adapted from CDPH, 2022a.

Note: Rates are per 100,000 population.

* Dash (–) indicates rates not calculated due to unknown population denominators.

Key: N = total number.

Disparities³⁷ in ARVs 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 uptake, adherence, and viral suppression by race/ethnicity, gender, gender identity/sexual orientation, and age.

Race or Ethnicity

Blacks in California are disproportionately affected by new HIV diagnoses with rates 4 times higher than Whites among men and nearly 9 times higher than Whites among women (CDPH, 2022a). Similarly, Latinos in California are disproportionately affected by new HIV diagnoses with rates nearly 2 times higher than Whites among men and 1.6 times higher than Whites among women (CDPH, 2022a). CHBRP found several studies indicating racial/ethnic disparities in ARV use and viral suppression among Blacks in California (CHRP, 2014; Landovitz et al., 2017). The California HIV/AIDS Research Program found that 34% of Blacks who were diagnosed with HIV in California achieved viral suppression, compared to 43% of Whites (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 Whites (91% vs 94%, respectively). Of these, less than half of Blacks (46%) had coverage for ARVs for 330 days compared to 52% of Whites. In sum, publicly insured Blacks living with HIV in California had significantly lower odds of obtaining ARVs compared to publicly insured Whites living with HIV (Landovitz et al., 2017).

Gender

Women in California – especially among Black and Latina women – are disproportionately affected by new HIV diagnoses compared to White women (CDPH, 2022a). Rates of HIV diagnoses among Black women (14.7) were nearly nine times as high as rates among White women (1.7) in 2018 (CDPH, 2020). Specific to Latina women, the rate of HIV diagnoses (2.7) were nearly twice as high as the rates among White women (1.7) in 2018 (CDPH, 2022a). Related to HIV treatment, disparities among Black and Latina women were also found in HIV linkages to care and viral suppression (CDPH, 2022a). Compared to White (75%) and Asian (81%) women, Black women had the lowest linkage to care (72%) within 1 month

³⁷ 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).

of HIV diagnosis followed by Latinas (74%). Similarly, only 56% of Black women achieved viral suppression in 6 months compared to 77% of Asian women (CDPH, 2022a). 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 Orientation³⁸

Of the subpopulations at highest risk for HIV, MSM – inclusive of gay, heterosexual, and bisexual men – experience disproportionate rates of HIV (CDC, 2021a).³⁹ Despite rates of new HIV diagnoses decreasing among Californian MSM during a 10-year time span (2008 to 2017), disparities among Black and Latino MSM newly diagnosed with HIV continue to persist (CDPH, 2019). In 2017, Black MSM were 3.5 times more likely to be diagnosed with HIV compared to White MSM. Similarly, Latino MSM were approximately twice as likely to be diagnosed with HIV compared to White MSM (CDPH, 2019). 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, 2019). For example, in 2017, 74% of Blacks were linked to HIV care within one month of diagnosis compared to 84% of Whites and 81% of Asians. Similarly, 58% of Blacks achieved viral suppression within 6 months of HIV diagnosis compared to 68% among Whites and 72% Asians (CDPH, 2019). Researchers attributed similar findings (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 ARVs; greater likelihood of reporting side effects with ARVs, and intentionally stopping ARVs for 2 or more days within a 12-month period) (Beer et al., 2016; Sullivan et al., 2021).⁴⁰ Quinn and Voisin (2020) found that poor adherence to ARVs among Black MSM was associated with stigma (and homonegativity), exposure to violence and trauma, and higher levels of substance use.

Age

Despite rates of new HIV diagnoses declining among all Californian age groups⁴¹ (except 25 to 34 year olds) over an 8-year time span, within the 13- to 24-year-old age range,⁴² Blacks had disproportionate rates of new HIV diagnoses compared to other race/ethnicities (CDPH, 2022a). More specifically, the rate of new HIV diagnoses among 13- to 24-year-old Blacks was nearly 6 times higher than the rate of HIV diagnoses among 13- to 24-year-old Whites (i.e., 48% vs. 8%, respectively) (CDPH, 2022a). Similarly, the 13- to 24- and 18- to 24-year-old age ranges have been found to have lower rates of linkages to care (and/or care retention) and sustained viral suppression, compared to other age groups (CDC, 2022c; CDPH, 2022a). According to the CDC, 18 to 24 year olds with HIV were found to have the highest percentage of missing at least one medical appointment within the past 12 months among all age groups

³⁸ 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).

³⁹ Per the CDPH (2020), it is estimated that both transgender women and men also experience disproportionate rates of HIV. Among Californian transgender people newly diagnosed with HIV (n = 71) in 2018, 86% were transgender women (CDPH, 2022a). Interestingly, compared to cisgender men (79%) and women (75%), transgender women had the highest linkage to care within 30 days of being newly diagnosed with HIV (CDPH, 2022a). CDPH (2020) did not report on HIV-related health outcomes specific to transgender men to preserve confidentiality.

⁴⁰ 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).

⁴¹ The California Department of Public Health categorizes HIV diagnoses via the following age groups: 13 to 24, 25 to 34, 35 to 44, 45 to 54, and 55 plus years (CDPH, 2022a).

⁴² It's important to note that, of the estimated 13% of people living with HIV in California who were aware of their HIV diagnosis in 2018, 45.3% (i.e., the highest percentage of undiagnosed) fell within the 13- to 24-year-old age range compared to 30.4% within the 25- to 34-year-old age range (CDPH, 2022a).

across the United States (CDC, 2022c). Additionally, 18 to 24 year olds with HIV had the lowest percentage in reported adherence to ARV medications over the past 30 days among all age groups across the United States (CDC, 2022c). 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). Racism, discrimination, HIV stigma, transphobia, homophobia, poverty, and level of education were all identified as age-related barriers to HIV care and related services (CDC, 2022c).

Barriers to Access and Use of Antiretrovirals to Prevent HIV/AIDS

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 were identified:

- Poor awareness and/or knowledge of PrEP;
- Low perception of HIV risk;
- Social stigma from primary care providers and/or family/partner/friends⁴³;
- 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, MS; St. Louis, MO; Providence, RI) 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.

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.

⁴³ 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 Access and Adherence to ARVs 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).

MEDICAL EFFECTIVENESS

As discussed in the Policy Context section, SB 427 would mandate coverage of U.S. Food & Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended HIV antiretroviral treatment medication. Health plans would not need to cover all the therapeutically equivalent versions without prior authorization or step therapy if they provide coverage for a noncovered therapeutic equivalent antiretroviral drug/device/product without cost sharing pursuant to an exception request. For nongrandfathered and grandfathered plans, the bill prohibits cost sharing and utilization management for FDA-approved or CDC-recommended antiretroviral drugs, devices, or products (including pre-exposure prophylaxis [PrEP] and postexposure prophylaxis [PEP]).

As discussed in the *Policy Context* section, SB 427 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover all FDA-approved or CDC-recommended antiretroviral drugs, products, and devices (ARVs) for HIV/AIDS with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

Additional information on disease/condition is included in the *Background Antiretrovirals for the Prevention and Treatment of HIV/AIDS* section. The medical effectiveness review summarizes findings from evidence⁴⁴ on the effects of cost sharing and utilization management on ARVs (including PrEP and PEP) use and adherence for patients with HIV and those at risk of contracting HIV.

Clinical Practice Guidelines for ARVs for HIV

The US. Department of Health and Human Services (DHHS, 2022) recommends that the primary goal of ARVs is to prevent HIV-associated morbidity and mortality and to reduce the risk of HIV transmission to sexual partners and to infants born to persons with HIV. This goal is accomplished by the use of ARVs to reduce and maintain a plasma HIV-1 RNA (viral load) below the quantification limits of commercially available tests. ARVs are widely accepted as effective treatment for the control of HIV as well as the prevention of transmission of HIV. The HHS guidelines also note that because of the numerous options for effective early therapy, selection of a regimen for a particular patient should be guided by factors such as virologic efficacy, toxicity, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, access, and cost.

The Panel on Antiretroviral Guidelines for Adults and Adolescents (Panel on ARVs, 2022) recommends initiating ARVs immediately (or as soon as possible) after HIV diagnosis⁴⁵ to increase the uptake of ARVs and linkage to care, decrease the time to viral suppression for individual patients, as well as to improve the rate of viral suppression among persons with HIV. To guide the selection of the initial ARV regimen, HIV drug-resistance testing is recommended at entry into care for people with HIV. Two large randomized controlled trials (START, 2015; TEMPRANO, 2015) show that when ARVs are initiated immediately (in patients with HIV who had CD4 T lymphocyte (CD4) cell counts >500 cells/mm³), there are significant reductions in morbidity and mortality.

⁴⁴ Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

⁴⁵ This refers to the period after an HIV diagnosis. For those that are HIV negative and who have had anal or vaginal sex in the past 6 months and have a sexual partner with HIV (especially if the partner has an unknown or detectable viral load), the CDC (CDC/USPHS, 2021) recommends that PrEP be considered. For HIV-uninfected persons after a nonoccupational exposure to blood, genital secretions, or other potentially infected body fluids of persons known to be HIV infected or of unknown HIV status, when that exposure represents a substantial risk for HIV acquisition, a 28-day course of PEP is recommended.

Long-term adherence to ARVs is essential to achieve durable virologic suppression and minimize drug resistance. Additionally, high plasma HIV RNA levels are a major risk factor for HIV transmission and, therefore, effective ARV adherence can lower both the presence of the virus in the blood and the risk of transmission of HIV to sexual partners and prevent perinatal transmission. There is research that shows that increased use of ARVs at the population level may lower the incidence of HIV and, subsequently, the prevalence of HIV on a community or population level. Additionally, viral suppression improves immune function, quality of life, lowers the risk of AIDS related complications, and allows persons with HIV to live a lifespan approaching that of persons without HIV (DHHS, 2022).

As previously discussed in the *Background*, guidelines suggest that initial ARVs regimens for persons with HIV start immediately, generally consisting of ARV drugs from one of two or three drug classes. Additionally, there is conclusive evidence that effective control of HIV, at both the individual and population level, relies on adherence to one of these accepted regimens.

CHBRP did not review literature on the effectiveness of ARVs because all ARVs medications have been approved by the FDA, and the efficacy of ARVs is well-established.

Research Approach and Methods

Studies of the impact of cost sharing and utilization management related to ARVs (including PrEP and PEP) were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English.

The search was limited to studies published from 2013 to present. Of the 791 articles found in the literature review, 20 were reviewed for potential inclusion in this report on SB 427 and a total of 12 studies were included in the medical effectiveness review for this report. For studies on the effectiveness of cost sharing and utilization management for PrEP and PEP, CHBRP reviewed studies published from 2019 to present because CHBRP had previously conducted thorough literature searches on these topics in 2019 for SB 159 and in 2018 for SB 1021. The other articles were eliminated because they did not focus on cost sharing or utilization management for ARVs (including PrEP and PEP), were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix C.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.⁴⁶ Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. For persons living with HIV infections, does cost sharing for HIV antiretroviral therapies affect uptake and adherence to CDC-recommended and FDA-approved ARVs?

⁴⁶ Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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- Is there any research that shows an impact on health care utilization and health outcomes?
 - 2. For persons living with HIV infections, does prohibiting utilization management for HIV antiretroviral therapies affect uptake and adherence to CDC-recommended and FDA-approved antiretroviral medications?
 - Is there any research that shows an impact on health care utilization and health outcomes?
 - 3. For persons at risk of contracting HIV or with a recent high-risk exposure, does cost sharing for antiretroviral therapies impact uptake and long-term adherence to PEP or PrEP?
 - 4. For persons at risk of contracting HIV or with a recent high-risk exposure, does utilization management of antiretroviral therapies affect uptake and adherence to PEP or PrEP?

Methodological Considerations

CHBRP did not review the evidence on the effectiveness of ARVs for the treatment of HIV, as this has been well documented, and is included in the widely accepted treatment guidelines as referenced in the “Clinical Practice Guidelines for HIV” section above.

Outcomes Assessed

The primary outcome of interest for the effect of cost sharing, step therapy, and utilization management on ARV use for patients with HIV is adherence to prescribed ARV regimens. The associated effect of ARV adherence on health was measured by using the medication possession ratio⁴⁷ (MPR), proportion of days covered (PDC⁴⁸), viral suppression, health care utilization (e.g., emergency department visits, hospitalizations), and HIV-related complications or comorbidities.

Study Findings

This following section summarizes CHBRP’s findings regarding the strength of evidence on the impact of cost sharing and utilization management for CDC recommended and FDA approved HIV antiretroviral therapies addressed by SB 427. CHBRP’s analysis of SB 339 (Analysis of California Senate Bill 339 HIV Preexposure Prophylaxis) evaluated the effectiveness of PrEP and PEP. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP’s conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP’s conclusion is based. Definitions of CHBRP’s grading scale terms is included in the box below, and more information is included in Appendix C.

The following terms are used to characterize the body of evidence regarding an outcome:

Clear and convincing evidence indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

⁴⁷ MPR is a ratio calculated as the ratio of the number of days a patient is stocked for their medication to the number of days a patient should be stocked for their medication.

⁴⁸ The proportion of days covered (PDC) is used to estimate medication adherence by looking at the proportion of days in which a person has access to the medication, over a given period of interest.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

Insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

More information is available in Appendix C.

Impact of Pill Regimen on ARVs Use and Adherence

A variety of factors can negatively affect medication adherence among people living with HIV (PLWH), such as pill burden, dosing frequency, side effect profiles, overall mental or physical health, and other patient-related and sociodemographic variables. Often times, to save on medication costs, patients will split their pill regimen into multiple pill regimen in order to use multiple generics instead of a single tablet equivalent (Cohen et al., 2013; Sweet et al., 2016). Research has reported that single-tablet regimens (STRs) to reduce pill burden is associated with improved adherence for PLWH compared with multiple-tablet regimens (MTRs) (Chu et al., 2017). A meta-analysis (Clay et al., 2018) (14 studies) reported that patients taking STRs were significantly more adherent (8 studies; odds ratio [OR] = 1.96; $p < 0.001$) and were more likely to achieve viral suppression (6 studies; relative risk [RR] = 1.05; $p = 0.002$) than those on MTRs. In meta-analysis, Altice et al. (2019) (8 studies), reported a 63% greater likelihood of achieving $\geq 95\%$ adherence (95% CI = 1.52-1.74; $p < 0.001$) and a 43% increase in the likelihood of achieving $\geq 90\%$ adherence (95% CI = 1.21-1.69; $p < 0.001$) in patients taking STRs versus MTRs.

In a retrospective study (Kangethe et al., 2019), researchers analyzed medical and pharmacy claims data (January 1, 2007, to June 30, 2016) of 332 Medicaid patients and 1,698 patients insured commercially. Researchers reported that more STR patients achieved $\geq 95\%$ adherence than MTR patients (<3-year follow-up, 53% vs. 39%; ≥ 3 -year follow-up, 61% vs. 45%; both $p < 0.001$). Chow et al. (2020) (2,633 subjects) examined predictors of low adherence (PDC <80%) using a logistic regression model and reported that patients initiating STR had higher 6-month adherence/persistence than those initiating MTR (OR = 1.69; $p = 0.022$).

Cost Sharing for Prescription Drugs

As discussed in the 2022 CHBRP report for Insulin Affordability (CHBRP, 2023), it is well established in the literature that persons who face higher cost sharing use fewer services than persons with lower cost sharing (CHBRP, 2018). In addition, there is a preponderance of evidence across multiple health conditions that, as cost sharing increases, adherence to drug regimens decreases, with a majority of studies indicating that decreased adherence is associated with worse outcomes (CHBRP, 2014). Goldman et al. (2007) found that for every 10% increase in cost sharing, there was a 2% to 6% decrease in utilization. The results are clear for those with chronic conditions that increased cost sharing is associated with decreased adherence and worse health outcomes (Goldman et al., 2007). Similar results were found in a meta-analysis of publicly insured patients (Sinnott et al., 2013). However, there is also evidence that the effect of cost sharing may differ depending on the specific disease and the specific drug (CHBRP, 2018).

Cost Sharing for ARVs and Long-Term Adherence and Viral Suppression

In a retrospective analysis of pharmacy refill dates using MPR to measure adherence, Cohen et al. (2013) (7,381 patients) reported that patients on STR had higher monthly costs versus patients on 2 or more pills per day ($p < 0.001$). Additionally, patients who were optimally adherent to ARVs were three times more likely than nonadherent patients to be virologically suppressed.

A propensity score-matched cohort study (Belenky et al., 2018) (801 women >65 years of age) examined how changes in out-of-pocket prescription drug spending affected ARVs adherence and viral suppression of dual eligibles after Medicare Part D implementation, compared to a matched sample of Medicaid-only enrollees. Transition to Medicare Part D was associated with a sharp increase in the proportion of dual eligibles with increased self-reported out-of-pocket prescription drug costs (0.24 vs 0.41 of enrollees; 0.20 difference-in-difference; $p < 0.001$). Despite the increase in out-of-pocket spending, the study reported both adherence and HIV viral load suppression remained stable during the study with no significant changes after implementation and no significant between-group differences.

In a retrospective observational cohort study (Johnston et al., 2012) (19,199 patient-quarters and 3,731 patients) using 2002-2008 data from a large U.S. claims database of commercially insured individuals examining adherence to ARVs (defined as the number of days within the quarter that a patient possessed all components of the initial ARVs regimen), researchers reported that increasing cost sharing⁴⁹ was associated with a modest, but clinically meaningful, decrease in adherence.⁵⁰ At the beginning of the study ($n = 3,117$), the predicted probabilities of at least 95% adherence were 0.782 for the lowest cost-sharing levels (\$25/month) versus 0.752 for the highest cost sharing level (\$144/month). At the seventh quarter (75th percentile of follow-up duration; $n = 1,096$ cases still under observation), for the lowest cost-sharing group, the predicted probabilities for 95% adherence were 0.773, versus 0.707 for the highest cost-sharing groups.

A prospective study of adults with HIV on ARVs (Lee et al., 2021) (364 subjects with undetectable plasma HIV viral load at study start) compared out-of-pocket health care expenditure, ARVs adherence, and virological failure⁵¹ in participants whose copayment for ARVs was reduced ($p < 0.001$) to participants whose copays did not change or participants who never had a medication copay. Compared to participants who never paid out-of-pocket copays or who always paid out-of-pocket copayments for medications, eliminating copays did not significantly change ARVs adherence or the incidence rate of virological failure. It is important to note that ARVs copayments declined significantly, but total out-of-pocket spending for HIV and non-HIV-related health care did not significantly change in the group that stopped copayments for ARVs, never had a copay, or the group with continued copayments after the policy change. Additionally, this study was conducted in Australia, which limits its generalizability to SB 427, due to the difference in the Australian and U.S. health care systems.

CHBRP did not find evidence of the impact of cost sharing on long-term medication adherence.

Summary of findings regarding the effect of cost sharing for ARVs on adherence and viral suppression: There is inconclusive evidence based on three cohort studies that PLWH with high deductibles were less likely to be adherent to ARVs therapy. Another study of women who are older than 65 years showed no difference in adherence when copay changed. One study in Australia showed no difference in adherence or viral suppression when copay decreased.

⁴⁹ Cost sharing amount was calculated per 30-day supply of the entire ARVs regimen for a patient. Cost-sharing levels of \$25 and \$144, represented the 25th and 90th percentiles of the cost-sharing distribution.

⁵⁰ Adherence was dichotomized for analysis at the clinically meaningful thresholds of 95% and 78%.

⁵¹ A type of HIV treatment failure. Virologic failure occurs when antiretroviral therapy (ARVs) fails to suppress and sustain a person's viral load to less than 200 copies/mL. Factors that can contribute to virologic failure include drug resistance, drug toxicity, and poor adherence to ARVs (NIH, 2022).

Figure 2. Effectiveness of Cost Sharing for ARVs on Long-Term Adherence and Viral Suppression



Cost Sharing for ARVs (Including PrEP and PEP) and Health Care Utilization

CHBRP did not find any studies of the impact of cost sharing on ARVs utilization.

One study examined the impact of cost sharing for ARVs on the impact of the use of other health services by PLWH. In a longitudinal cohort study of newly enrolled PLWH in a large integrated health care system in Northern California (Satre et al., 2020) (880 patients), researchers examined use of health care, deductibles (none, \$1 to \$999 and \geq \$1,000), and 3-year patterns of health service utilization (primary care, psychiatry, substance treatment, emergency, inpatient). Health care use was greatest immediately after enrollment and decreased over 3 years. PLWH with high deductibles were less likely to use primary care (OR = 0.79, 95% CI = 0.49-0.84; $p < 0.01$) or psychiatry (OR = 0.52, 95% CI = 0.27-1.01; $p = 0.05$) than those with no deductible. There were no significant differences in hospitalization, emergency department (ED) use, and substance use treatment visits for those with high deductibles compared to low deductibles.

Summary of findings regarding the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization: There is *insufficient* evidence based on one study that PLWH with high deductibles were less likely to use primary care, but there was no difference in hospitalization, ED use, and substance use treatment.

Figure 3. Effectiveness of Cost Sharing for ARVs on Health Care Utilization



Cost Sharing for ARVs (Including PrEP and PEP) and Health Outcomes

CHBRP found no recent studies that analyzed the impact of cost sharing of ARVs (including PrEP and PEP) on health outcomes (other than viral suppression).

Summary of findings regarding the effect of cost sharing for ARVs (including PrEP and PEP) on health outcomes: There is insufficient evidence on the effect of cost sharing of ARVs (including PrEP and PEP) on health outcomes.

Figure 4. Effectiveness of Cost Sharing for ARVs (Including PrEP and PEP) on Health Outcomes



Effect of Utilization Management on Adherence and Uptake of ARVs (Including PrEP and PEP)

CHBRP found no recent studies that analyzed the impact of prior authorization on the adherence or uptake of PrEP, PEP, or other ARVs. However, one study from the report for SB 159 analyzed prior authorizations among patients at an HIV clinic who were prescribed medication to treat HIV. The clinic received 288 requests for prior authorization for 144 patients. Thirty-seven (13%) of the prior authorization requests were for HIV antiretroviral medications, and 32 (86%) of these were approved. All five denials of prior authorization for antiretroviral medications involved fixed-dose combinations of medications⁵². In all cases, the health plan denied the authorization because its formulary included the single medications present in the fixed dose combinations. Across all types of medication, the average length of time to process a prior authorization was 3.1 days; this length of time differed between Medicaid (mean time required, 2.1 days) and commercial plans (mean time required, 6.3 days; p = 0.034) (Raper et al., 2010). These delays constrained the clinic’s ability to promptly provide life-saving medications to people with HIV.

Summary of findings regarding the effect of utilization management on adherence and uptake of ARVs (Including PrEP and PEP): There is insufficient evidence on the impact of prior authorization on the adherence and uptake of PrEP, PEP, or other ARVs.

Figure 5. Effectiveness of Utilization Management on Adherence and Uptake of ARVs (Including PrEP and PEP)



Effect of Utilization Management of ARVs (Including PrEP and PEP) on Health Care Utilization and Health Outcomes

CHBRP did not find any evidence on the impact of utilization management of ARVs (Including PrEP and PEP) on health care utilization and health outcomes.

Summary of findings regarding the effect of utilization management of ARVs (Including PrEP and PEP) on health care utilization and health outcomes: There is insufficient evidence on the effect of cost sharing of ARVs (including PrEP and PEP) on health outcomes.

Figure 6. Effect of Utilization Management of ARVs (Including PrEP and PEP) on Health Care Utilization and Health Outcomes



⁵² Combination products, also known as fixed-dose drug combinations (FDCs), are combinations of two or more active drugs in a single dosage form. The U.S. Food and Drug Administration defines a combination product as “a product composed of any combination of a drug and a device or a biological product and a device or a drug and a biological product or a drug, device, and a biological product” (WHO, 2006).

Summary of Findings

CHBRP found inconclusive evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.

CHBRP found insufficient evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes.

CHBRP found insufficient evidence on the effect of utilization management for ARVs (including PrEP and PEP) health care utilization and health outcomes.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 427 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover antiretroviral therapy (ARVs) for HIV/AIDS with no cost sharing for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies that offer a pharmacy benefit. For grandfathered DMHC-plans and CDI-policies with a pharmacy benefit that do not currently offer coverage for ARVs, SB 427 requires that they add coverage for ARVs to their plans and policies.

In addition to commercial enrollees, more than 73% of enrollees associated with the California Public Employees' Retirement System (CalPERS) and more than 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.⁵³ Although the benefit coverage for beneficiaries with DMHC-regulated Medi-Cal plans is subject to SB 427, their pharmacy benefit is carved out and administered under Medi-Cal Rx, and therefore, SB 427 would not impact their benefit coverage.

This section reports the potential incremental impacts of SB 427 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

In this analysis, CHBRP assumes that ARVs includes oral pre-exposure prophylaxis (PrEP), oral postexposure prophylaxis (PEP), and long-acting cabotegravir (CAB-LA) as discussed in the *Background* section. CAB-LA is administered to enrollees by primary care physicians as administration involves an intramuscular injection. Although oral PrEP and PEP are most often prescribed by a primary care provider, the prescriptions are filled by pharmacists who, because of SB 159 (2019) already have the ability to furnish oral PrEP and PEP for 60 days without the involvement of a primary care physician. This analysis assumes that this will continue and that there will not be any change in providers who administer or furnish ARVs. CHBRP's analysis focuses on the elimination of cost sharing among enrollees who currently use ARVs for nongrandfathered and grandfathered DMHC-regulated plans and CDI-regulated policies. CHBRP also recognizes that some grandfathered plans will be required to newly offer coverage postmandate if a pharmacy benefit is already present. Estimates for utilization and costs are based on Milliman data.

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

Baseline and Postmandate Benefit Coverage

At baseline, 100% of enrollees (22,842,000) in DMHC-regulated health plans and CDI-regulate policies have health insurance subject to SB 427 (see Table 1). Of these, 98.9% (22,599,704) have coverage for ARVs. At baseline, 38.6% (8,817,000) of enrollees have coverage for ARVs that is fully compliant with SB 427. Postmandate, 100% of enrollees with coverage subject to SB 427 would have coverage for ARVs without cost sharing.

Baseline and Postmandate Utilization

Almost all – 95.6% – 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

⁵³ For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

prescription medications.⁵⁴ Another 1.2% do not have a pharmacy benefit, and 3.2% have a pharmacy benefit that is not regulated by DMHC or CDI. Because SB 427 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 compliant.

At baseline, CHBRP estimates that 130,731 enrollees per year in DMHC-regulated plans and CDI-regulated policies used ARVs with cost sharing. Among these, 49,257 enrollees per year used ARVs with cost sharing and 97,658 enrollees used ARVs with no cost sharing (see Table 1). It is important to note that these two groups had some overlap (16,184 enrollees), as some enrollees had cost sharing during the year until hitting their maximum out-of-pocket limit, and then had no cost sharing for the remainder of the year. On average, each enrollee with cost sharing had 7.6 prescriptions annually with cost sharing at baseline, with an average of 6.5 prescriptions for enrollees with no cost sharing. The average number of 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. Finally, 0.2% of all enrollees utilized ARVs with cost sharing at baseline, as well as 0.4% of enrollees using ARVs with no cost sharing. This translates to an overall annual utilization of 372,340 ARVs prescriptions with cost sharing and 633,832 ARVs prescriptions without cost sharing at baseline (see Table 1).

A total of 0.6% of all enrollees in DMHC-regulated health plans and CDI-regulated policies utilize ARVs. Postmandate, CHBRP projects that an additional 1,402 enrollees would utilize ARVs annually without incurring any cost sharing, resulting in a 1% increase in utilization (or a total utilization of approximately 132,133 enrollees). On average, each enrollee utilizing ARVs would have 7.7 prescriptions with no cost sharing using a denominator of the entire enrollee population, resulting in a total of 1,016,959 ARVs prescriptions annually postmandate, representing a 1% increase in total prescriptions.

Baseline and Postmandate Per-Unit Cost

At baseline, CHBRP estimates that the average annual total cost for ARVs is \$19,684 for ARVs with cost sharing, with an average annual cost share of \$1,273. For enrollees without cost sharing for ARVs at baseline, the average cost at baseline for ARVs is \$10,280. This reduced cost is due to a combination of factors, including fewer prescriptions (6.5 versus 7.6 among those with cost sharing at baseline) and coverage of different types of ARVs, such as a low-cost generic version of Truvada. Postmandate, CHBRP estimates that the average annual cost for ARVs will be \$15,116, with no cost share.

Baseline and Postmandate Expenditures

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies, with Table 6 focusing on the marginal impact of SB 427. 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).

SB 427 would increase total net annual expenditures by \$51,601,000, or 0.0352%, for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$157,254,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$105,653,000 decrease in enrollee expenses for covered and/or noncovered benefits.

⁵⁴ For more detail, see CHBRP’s resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

Premiums

Changes in premiums as a result of SB 427 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to SB 427.

Among DMHC-regulated commercial plans, premium increases postmandate range from \$0.6638 PMPM for large group plans to \$1.5138 PMPM for individual plans. Among CDI-regulated policies, premium increases range from \$1.0586 PMPM for large-group policies to \$2.1915 PMPM for individual policies. Although CHBRP is aware that there may be some differential impact between grandfathered and nongrandfathered plans, a lack of data regarding specific impacts made CHBRP unable to quantify an estimated difference.

For enrollees associated with CalPERS in DMHC-regulated plans, premiums are expected to increase by \$0.5267 PMPM postmandate.

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.

Enrollee Expenses

SB 427–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 1, Table 5, and Table 6) with health insurance that would be subject to SB 427 expected to use ARVs during the year after enactment.

Although it is possible that some enrollees may have incurred expenses related to ARVs for which coverage was denied, CHBRP is unable to estimate the frequency of such situations and therefore cannot provide an impact calculation. CHBRP estimates that the postmandate decrease in enrollee expenses due to the elimination of cost sharing will range from \$0.2521 PMPM for DMHC-regulated small-group plans to \$0.8246 PMPM for enrollees in CDI-regulated individual policies.

Average enrollee out-of-pocket expenses per user

For enrollees with coverage for ARVs at baseline that included cost sharing, 80,768 enrollees (0.6% of enrollees on average among all DMHC-regulated plans and CDI-regulated policies) would experience an average decrease in cost sharing of \$2,145 (see Table 4). CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

Enrollees who have coverage at baseline that includes cost sharing would experience a decrease in their average out-of-pocket expenses for covered services. The amount of the reduction varies but is estimated to range from \$882 for enrollees in DMHC-regulated CalPERS plans to \$4,047 for enrollees in DMHC- or CDI-regulated individual plans and policies (Table 4).

Table 4. Impact of SB 427 on Average Annual Enrollee Out-of-Pocket Expenses Per User

	Large Group	Small Group	Individual	CalPERS	Medi-Cal
% of Enrollees with out-of-pocket expenses impact due to SB427 (a)	0.35%	0.36%	0.36%	0.35%	0.00%
Average annual out-of-pocket expenses impact for enrollees (b)	-\$1,273	-\$3,397	-\$4,047	-\$882	\$0

Source: California Health Benefits Review Program, 2023.

Notes: Average enrollee out-of-pocket expenses include expenses for both covered and noncovered benefits.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

Key: CalPERS = California Public Employees' Retirement System.

Postmandate Administrative Expenses 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.

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 1, Table 5, and Table 6), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 427.

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 SB 427.

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

CHBRP is aware of public programs that are focused on HIV/AIDS-related expenses, which could include PrEP/PEP, but these programs are tailored to provide low-cost services to people who are uninsured and are therefore outside of CHBRP's analysis. CHBRP is aware that programs such as the AIDS drug Assistance Program (ADAP) may also provide coverage for PrEP, PEP, and other ARVs to commercially-insured enrollees, but is unable to quantify how many enrollees in DMHC-regulated plans or CDI-regulated policies are using this program rather than their insurance, potentially for reasons concerning privacy of medical information. It should be noted that cost sharing for ARVs has a differential impact among enrollees; lower-income enrollees will find it more difficult to pay any cost sharing (Ghosh et al., 2019).

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans Medi-Cal (Excludes COHS) (c)			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Under 65	65+	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB427	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Premium costs										
Average portion of premium paid by employer (e)	\$473.17	\$417.10	\$0.00	\$581.85	\$254.61	\$543.16	\$490.57	\$517.32	\$0.00	\$93,424,638,000
Average portion of premium paid by enrollee	\$122.17	\$180.13	\$645.33	\$113.49	\$0.00	\$0.00	\$180.61	\$168.99	\$626.90	\$39,493,007,000
Total premium	\$595.34	\$597.23	\$645.33	\$695.34	\$254.61	\$543.16	\$671.18	\$686.31	\$626.90	\$132,917,645,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$40.98	\$127.06	\$168.73	\$49.17	\$0.00	\$0.00	\$99.22	\$184.48	\$208.51	\$13,857,141,000
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	\$636.33	\$724.29	\$814.06	\$744.50	\$254.61	\$543.16	\$770.40	\$870.80	\$835.40	\$146,774,786,000

Source: California Health Benefits Review Program, 2023.

(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 51.7% are state retirees, state employees, or their dependents. About one in five (22.5%) of these enrollees has a pharmacy benefit not subject to DMHC. 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.

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(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 will be newly covered, postmandate. Other components of expenditures in this table includes all health care services covered by insurance.

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

Table 6. Postmandate Per Member Per Month Premiums and Total expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (Excludes COHS) (c)		Large Group	Small Group	Individual	
					Under 65	65+				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 427	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Premiums										
Average portion of premium paid by employer (e)	\$0.5276	\$0.8802	\$0.0000	\$0.4407	\$0.0000	\$0.0000	\$0.7737	\$1.1600	\$0.0000	\$81,213,000
Average portion of premium paid by enrollee	\$0.1362	\$0.3801	\$1.5138	\$0.0860	\$0.0000	\$0.0000	\$0.2849	\$0.3789	\$2.1915	\$76,041,000
Total premium	\$0.6638	\$1.2603	\$1.5138	\$0.5267	\$0.0000	\$0.0000	\$1.0586	\$1.5390	\$2.1915	\$157,254,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	-\$0.3535	-\$1.0083	-\$1.1920	-\$0.2564	\$0.0000	\$0.0000	-\$0.7023	-\$1.2312	-\$1.3668	-\$105,653,000
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	\$0.3103	\$0.2521	\$0.3218	\$0.2703	\$0.0000	\$0.0000	\$0.3563	\$0.3078	\$0.8246	\$51,602,000
Percent change										
Premiums	0.1115%	0.2110%	0.2346%	0.0757%	0.0000%	0.0000%	0.1577%	0.2242%	0.3496%	0.1183%
Total expenditures	0.0488%	0.0348%	0.0395%	0.0363%	0.0000%	0.0000%	0.0463%	0.0353%	0.0987%	0.0352%

Source: California Health Benefits Review Program, 2023.

(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 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁵⁵ 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.⁵⁶

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(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 will 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.

⁵⁵ For more detail, see CHBRP's resource, *Estimates of Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

⁵⁶ For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 427 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover all U.S. Food & Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended antiretroviral drugs, products, and devices (ARVs) for HIV/AIDS with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact⁵⁷ of SB 427 on ARV adherence and viral suppression, health care utilization, and HIV-related complications and comorbidities. See *Long-Term Impacts* for discussion of premature death.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 427 include adherence to prescribed ARV regimens and viral suppression, health care utilization, and HIV-related complications or comorbidities.

As presented in the *Medical Effectiveness* section:

- CHBRP did not review literature on the effectiveness of ARVs because all ARV medications have been approved by the FDA, and the efficacy of ARVs is well-established.
- CHBRP found *inconclusive evidence* on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.
- CHBRP found *insufficient evidence* on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes.
- CHBRP found *insufficient evidence* on the effect of utilization management for ARVs (including PrEP and PEP) health care utilization and health outcomes.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, at baseline 100% (22,842,00) of enrollees with health insurance would have coverage subject to SB 427. Of these, 98.9% have coverage for ARVs. At baseline 38.6% of enrollees have coverage for ARVs that is fully compliant with SB 427. Postmandate, 100% of enrollees with coverage subject to SB 427 would have coverage for ARVs without cost sharing. Due to this change in benefit coverage, CHBRP estimates an additional 1,402 enrollees will utilize ARVs (equal to 132,133 enrollees overall), representing a 1% increase in enrollees using ARVs overall. The total percent of enrollees using ARVs is 0.6% of all enrollees. On average, enrollees who use ARVs would obtain 7.7 prescriptions without cost sharing using a denominator of the entire enrollee population. This translates to an overall utilization of 1,016,959 ARVs prescriptions without cost sharing, postmandate, representing a 1% increase in ARV prescriptions.

As presented in the *Background* section, uptake and long-term adherence to ARVs for the prevention of HIV promotes a reduction in HIV infection among those with repeated, intimate exposure to HIV-positive individuals or other high-risk individuals of unknown status. Similarly, early uptake and long-term adherence to ARVs for the treatment of HIV/AIDS promotes an increase in control in infection; suppression of viral replication; reduction in transmission of disease to a noninfected sexual partner; and a reduction in HIV-related morbidity and mortality during all stages of HIV. Given the anticipated increase in utilization, there will be:

⁵⁷ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

- An increase in the number of individuals who do not seroconvert due to PrEP and PEP access (i.e., an increase in the number of people – who are at high risk for HIV – who access PrEP and PEP, thereby avoiding HIV infection);
- An increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (i.e., an increase in the number of people infected with HIV who access HIV treatment); and
- A subsequent decrease in both short- and long-term adverse health outcomes (e.g., opportunistic cancers) as well as a decrease in the transmission of HIV to noninfected sexual partners.

In the first year postmandate, CHBRP estimates an additional 1,402 enrollees would seek ARVs overall for the prevention or treatment for HIV/AIDS. This includes an increase in the number of individuals who do not seroconvert due to PrEP (47) and PEP (22) access, an increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (1,332),⁵⁸ and a subsequent decrease in both short- and long-term adverse health outcomes (including a reduction in the transmission of HIV to noninfected sexual partners). This estimate is supported by FDA approval of all ARV medications for the prevention and treatment of HIV/AIDS (and their established efficacy) and an estimated 1% increase in ARVs utilization overall.

Impact on Disparities⁵⁹

As described in the *Background* section, disparities in ARVs uptake, adherence, and viral suppression exist by race/ethnicity, gender, gender identity/sexual orientation, and age. CHBRP is unable to estimate SB 427's impact on disparities related to race/ethnicity, gender, gender identity/sexual orientation, or age in the first 12 months postmandate

Impact on Racial or Ethnic Disparities

Although racial/ethnic disparities exist in ARV use, adherence, and viral suppression, CHBRP found no studies that discuss the impact of cost sharing and utilization management on racial/ethnic disparities in ARV utilization.

The impact of SB 427 on reducing documented disparities among racial and ethnic groups (see the *Background* section) is unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARV utilization among newly covered enrollees.

Impact on Gender

Although gender disparities exist in ARV use, adherence, and viral suppression—especially among Black and Latina women – CHBRP found no studies that discuss the impact of cost sharing and utilization management on gender disparities in ARV utilization.

The extent to which gender disparities may be impacted by SB 427 is unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARV utilization among newly covered enrollees.

⁵⁸ CHBRP assumes no overlap in the utilization of PrEP, PEP, or ARVs among newly eligible enrollees.

⁵⁹ For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: www.chbrp.org/about/analysis-methodology/public-health-impact-analysis.

Impact on Gender Identity or Sexual Orientation

Although gender identity / sexual orientation disparities exist in ARVs use, adherence, and viral suppression – especially among Black men who have sex with men (MSM) – CHBRP found no studies that discuss the impact of cost sharing and utilization management on gender identity / sexual orientation disparities in ARVs utilization.

The extent to which gender identity and sexual orientation disparities may be impacted by SB 427 is unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARVs utilization among newly covered enrollees.

Impact on Age

Although age disparities exist in ARV use, adherence, and viral suppression – especially among youth and young transgender women and MSM, aged 13 to 24 years – CHBRP found no studies that discuss the impact of cost sharing and utilization management on age disparities in ARVs utilization.

The extent to which age disparities may be impacted by SB 427 is unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARV utilization among newly covered enrollees.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 427, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

The utilization increases estimated in this report are not expected to be different over the long-term. However, over time, adherence to antiretroviral therapy (ARVs) may improve as cost sharing will no longer be a barrier, which could lead to an increase in overall annual utilization. It should be noted, however, that this effect would be limited since adherence is also dependent on various other factors mentioned in the *Background* section, such as the severity of side effects and access to health care, which can be hindered by barriers beyond cost sharing, such as transportation and paid sick time.

Cost Impacts

Cost impacts over the long term would be proportional to any increase in utilization and are not anticipated to change after the first year postmandate. Although additional use of and adherence to ARVs will prevent HIV infection and later AIDs-related diseases, the marginal impact of SB 427 over the existing use of ARVs cannot be quantified. Additionally, the vast array of AIDS-related diseases that could occur and would be prevented cannot be quantified, but in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to SB 427.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts disparities, premature death, and economic loss.

In the case of SB 427, CHBRP estimates an additional 1,402 enrollees (equal to 132,133 enrollees overall) would utilize ARVs, representing a 1% increase in overall ARVs utilization. On average, enrollees who use ARVs will obtain 7.7 prescriptions per person without cost sharing. This translates to an overall utilization of 1,016,959 ARVs prescriptions without cost sharing, postmandate.

Therefore, the long-term public health impacts are likely to include a reduction in future HIV transmissions (i.e., reduction in HIV incidence among those using PrEP and PEP), increased uptake and adherence to ARVs (leading to a subsequent reduction in the number of overall adverse health outcomes in the long-term), as well as a reduction in downstream effects such as impacts on premature death.

Impacts on Premature Death

Premature death

Premature death, measured by years of potential life lost, is often defined as death occurring before the age of 75 years (NCI, 2019).⁶⁰ Because HIV is known to weaken a person's immune system by progressively depleting important cells that fight disease and infection, if left untreated,⁶¹ individuals with HIV that progresses to AIDS can experience severe health outcomes – which can ultimately lead to mortality – with a survival rate of up to 3 years (CDC, 2019). According to the California Department of Public Health (CDPH, 2022a), the annual number of deaths of persons with HIV infection⁶² decreased from 1,864 in 2016 to 1,806 in 2020 (equal to 4.5 per 100,000 population). As mentioned in the *Background*, early diagnosis, prompt treatment, and continued linkages to care and treatment all play a major role in reducing HIV/AIDS-related mortality. Given the anticipated short-term public health impacts, there is a strong likelihood that SB 427 could reduce barriers to ARVs access and sustained HIV care over the long-term, leading to additional downstream effects (i.e., a reduction in HIV/AIDS-related premature death), although the exact impact is unknown.

⁶⁰ For more information about CHBRP's public health methodology, see <https://www.chbrp.org/about/analysis-methodology/public-health-impact-analysis>.

⁶¹ As mentioned in the *Background* section, life expectancy for individuals with HIV who receive ARVs can approach that of the general population.

⁶² The data on HIV deaths of persons with diagnosed HIV infection represent all causes of death and may not be related to HIV infection.

APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2023, the California Senate Committee on Health requested that CHBRP analyze SB 427, as amended on March 21, 2023.

AMENDED IN SENATE MARCH 21, 2023

CALIFORNIA LEGISLATURE— 2023–2024 REGULAR SESSION

SENATE BILL

NO. 427

Introduced by Senator Portantino

February 13, 2023

An act to amend Section 1342.74 of the Health and Safety Code, and to amend Section ~~10169~~ 10123.1933 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 427, as amended, Portantino. ~~Independent medical review.~~ Health care coverage: antiretroviral drugs, devices, and 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 or health insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, 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 would prohibit a health care service plan or health insurer from subjecting antiretroviral drugs, devices, or 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 AIDS/HIV to prior authorization or step therapy, 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 insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. The bill 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 antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV. The bill would require a grandfathered health care service plan contract or health insurance policy to provide coverage for those drugs, devices, or products, and would require a plan or insurer to provide coverage under the outpatient prescription drug benefit for those drugs, devices, or products, including by supplying participating providers directly with a drug, device, or product, as specified. 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.

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.

~~Existing law provides for the regulation of disability insurers by the Department of Insurance. Existing law establishes the Independent Medical Review System in the department to review grievances involving a disputed health care service. Under existing law, a statement of decision regarding denying, modifying, or delaying health care services, based in whole or in part on a finding that a proposed health care service is not a covered benefit under the contract, is required to clearly specify the provision in the contract that excludes that coverage.~~

~~This bill would make technical, nonsubstantive changes to those provisions and would clarify that the above-described statement of decision is required to clearly specify the provision in the contract that excludes a specific coverage.~~

Vote: majority Appropriation: no Fiscal Committee: ~~no~~yes Local Program: ~~no~~yes

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

SECTION 1. *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 ~~that are medically necessary~~ drugs, devices, or 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 AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) ~~If the United States Food and Drug Administration~~ FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, 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.~~ *therapy and the plan provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request.*

(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 not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(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 the health care service plan has an out-of-network pharmacy benefit.

(e) (1) A nongrandfathered health care service plan contract shall not impose any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure 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, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis of HIV.

(f) A health care service plan shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including by supplying participating providers directly with a drug, device, or 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 does not cover an essential health benefit, as defined by Section 1367.005, or a Medicare supplement policy.

(2) This section applies to a Medi-Cal managed care plan that contracts with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(3) This section applies regardless of whether or not an antiretroviral drug, device, or product is self-administered.

(h) The department and director 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 department assesses a civil penalty for a violation, any hearing that is requested by the plan shall be conducted by the Office of Administrative Hearings. This subdivision does not impair or restrict the department's authority pursuant to another provision of this code or the Administrative Procedure Act.

SEC. 2. *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 that are medically necessary~~ drugs, devices, or 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 AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) ~~If the United States Food and Drug Administration~~ FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, 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~~. *therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request.*

(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) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) (1) A nongrandfathered health insurance policy shall not impose any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure 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, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis of HIV.

(e) A health insurer shall provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including by supplying participating providers directly with a drug, device, or product that is required by this section and is not self-administered.

(f) This section does not apply to a specialized health insurance policy that does not cover an essential health benefit, as defined by Section 10112.27, or a Medicare supplement policy. This section applies regardless of whether or not an antiretroviral drug, device, or product is self-administered.

(g) 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 shall 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.

SEC. 3.*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.*

APPENDIX B HIV ANTIRETROVIRAL DRUG CLASSES

Antiretroviral therapy (ARVs) is comprised of more than 30 antiretroviral drugs in eight FDA-approved drug classes for treatment of HIV infection (DHHS, 2022). The eight FDA-approved drug classes are identified below:

1. **Nucleoside Reverse Transcriptase Inhibitors (NRTIs):** In NRTIs, the HIV reverse transcriptase – an important HIV enzyme that converts HIV RNA into DNA – is blocked, preventing HIV from replicating.
2. **Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs):** In NNRTIs, the inhibitors bind to the HIV reverse transcriptase, which prevents HIV from replicating.
3. **Protease Inhibitors (PIs):** In PIs, HIV protease, which is another HIV enzyme that breaks down proteins into smaller units that combines with HIV genetic material to form a new HIV virus, is blocked.
4. **Fusion Inhibitors:** Fusion inhibitors block HIV from entering and attacking CD4 cells.
5. **CCR5 Antagonists:** CCR5 antagonists block HIV from binding onto CCR5 coreceptors on the surface of CD4 cells that allows it to enter the cells.
6. **Integrase Strand Transfer Inhibitors (INSTIs):** In INSTIs, HIV integrase enzyme is blocked to prevent HIV from inserting its viral DNA into CD4 cells.
7. **Attachment Inhibitors:** Attachment inhibitors bind to the gp120 protein that is on the outer surface of HIV, preventing HIV from entering CD4 cells.
8. **Post-Attachment Inhibitors:** In post-attachment inhibitors, CD4 receptors are blocked to prevent HIV from entering.

Pharmacokinetic Enhancers: Pharmacokinetic enhancers (also known as boosters) increase the effectiveness of HIV medicines. Pharmacokinetic enhancers are included in an HIV treatment regimen, which includes combination HIV medicines.

APPENDIX C LITERATURE REVIEW METHODS

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the effects of CDC recommended and FDA approved HIV antiretroviral therapies to prevent and treat HIV, addressed by SB 427 were identified through searches of PubMed, CINAHL Complete, Web of Science Core Collection, EconLit, Business Source Complete. The search was limited to abstracts of studies published in English and in the studies in the United States. The search was limited to studies published from 2013 to present. The literature on the medical effectiveness of cost sharing and utilization management on the use of ARVs and the subsequent health care utilization and health outcomes did not include any randomized controlled trials. The majority of the papers returned were observational cohort studies.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 791 articles, of which 20 were reviewed for inclusion in this report. A total of 11 studies were included in the medical effectiveness review for SB 427: A total of 12 studies since 2019 were included in the medical effectiveness review for the effectiveness of PrEP and PEP.

Medical Effectiveness Evidence Grading System

In making a “call” for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.⁶³ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence;* and
- *Insufficient evidence.*

⁶³ Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

APPENDIX D 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.⁶⁴ 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 at CHBRP's website.⁶⁵

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 antiretroviral therapy (ARVs) was assessed by a survey of the largest commercial health plans and health insurers in California. Responses to this survey represented 54.9% of DMHC-regulated commercial plans and 0.0% of CDI-regulated policies that can be subject to state benefit mandates. CHBRP assumed that Medi-Cal plans are fully compliant with the requirements of SB 427. As necessary, CHBRP extrapolated from responses of similarly situated plans/policies.

For this analysis, CHBRP relied on CPT® codes to identify relevant services. CPT copyright 2022 American Medical Association. All rights reserved. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

CHBRP identified ARVs by National Drug Code (NDC) and classified the drugs according to Table 7 below. CHBRP relied upon Milliman's Consolidated Health Cost Guidelines Sources Database (CHSD) commercial California experience for this analysis.

Table 7. Antiretroviral Therapies

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

⁶⁴ CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

⁶⁵ See method documents posted at www.chbrp.org/about/analysis-methodology/cost-impact-analysis; in particular, see *2022 Cost Analyses: Data Sources, Caveats, and Assumptions*.

NRTI combination products	Tenofovir disoproxil fumarate/emtricitabine
NRTI combination products	Tenofovir disoproxil fumarate/lamivudine
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
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
Fusion inhibitor	Emfivortide
CCR5 antagonist	Maraviroc
CD4-directed post-attachment inhibitor	Ibalizumab-uiyk
gp120-directed attachment inhibitor	Fostemasavir
Coformulated combination products as single-tablet regimens	Bictegravir/tenofovir alafenamide/emtricitabine
Coformulated combination products as single-tablet regimens	Darunavir/cobicistat/tenofovir alafenamide/emtricitabine
Coformulated combination products as single-tablet regimens	Dolutegravir/abacavir/lamivudine
Coformulated combination products as single-tablet regimens	Dolutegravir/lamivudine

Coformulated combination products as single-tablet regimens	Dolutegravir/rilpivirine
Coformulated combination products as single-tablet regimens	Doravirine/tenofovir disoproxil fumarate/lamivudine
Coformulated combination products as single-tablet regimens	Efavirenz/tenofovir disoproxil fumarate/emtricitabine
Coformulated combination products as single-tablet regimens	Efavirenz/tenofovir disoproxil fumarate/lamivudine
Coformulated combination products as single-tablet regimens	Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine
Coformulated combination products as single-tablet regimens	Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine
Coformulated combination products as single-tablet regimens	Rilpivirine/tenofovir alafenamide/emtricitabine
Coformulated combination products as single-tablet regimens	Rilpivirine/tenofovir disoproxil fumarate/emtricitabine
Copackaged combination products as injectable regimens	Cabotegravir + rilpivirine
Pharmacokinetic enhancers (boosters)	Cobicistat
Pharmacokinetic enhancers (boosters)	Ritonavir

Source: California Health Benefits Review Program, 2023.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes all individuals with health insurance regulated by the DMHC or CDI, including commercial, CalPERS and Medi-Cal. SB 427 requires coverage of ARVs “drugs and devices”. No FDA-approved antiretroviral therapy devices exist at this time, and CHBRP made no assumption about the coverage or utilization of such devices for this analysis.
- CHBRP surveyed managed commercial plans and insurers to determine the percentage of the population with coverage for provision of ARVs with and without cost sharing. Commercial plans indicated coverage of ARVs with cost sharing varies between 89% and 100% by market segment, while coverage without cost sharing varies between 0% and 100%.

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- No 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 did not survey managed Medi-Cal organizations for this analysis but assumes 100% compliance with SB 427.
 - CHBRP assumed that CalPERS coverage and cost sharing would be equal to non-grandfathered large group DMHC plans.

Methodology and Assumptions for Baseline Utilization

- The average annual utilization for ARVs (by NDC code) were identified in Milliman's proprietary 2021 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD) for commercial members in California. Due to low utilization of these codes in the Medicaid data, the utilization rate from the Medicaid population was assumed equal to Commercial rate. Note that SB 427 will not impact managed Medi-Cal plans as they are assumed compliant in the baseline.
- The utilization rates were trended at 0.00% from 2021 to 2024.

Methodology and Assumptions for Baseline Cost

- CHBRP calculated the average California commercial cost per service for ARVs (by NDC code) and using Milliman's proprietary 2021 Consolidated Health Cost Guidelines™ Sources Database (CHSD).
- The average costs per service were trended at 2.85% annually from 2021 to 2024.

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 was assumed for the baseline scenarios.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed the utilization rate for enrollees with coverage postmandate is equal to the utilization rate for enrollees with coverage at baseline.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per prescription would not change as a result of SB 427.

Methodology and Assumptions for Postmandate Cost Sharing

- SB 427 prohibits cost sharing on ARVs drugs and devices.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask plans and insurers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

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

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 427 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of SB 427 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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