

California Health Benefits Review Program

Analysis of California Senate Bill 1021 Prescription Drugs

A Report to the 2017-2018 California State Legislature

April 9, 2018



Key Findings:

Analysis of California Senate Bill 1021 Prescription Drugs

Summary to the 2017–2018 California State Legislature, April 9, 2018



AT A GLANCE

The version of California Senate (SB) Bill 1021 analyzed by CHBRP would eliminate the sunset of January 1, 2020, for provisions enacted through the passage of Assembly Bill (AB) 339 in 2015; would require plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CD) to cover medications to prevent HIV/AIDS; and includes other cost-sharing provisions.

1. CHBRP estimates that, in 2019, of the 23.4 million Californians enrolled in state-regulated health insurance, a maximum of 15.9 million of them would have insurance subject to SB 1021.
2. **Benefit coverage.** 100% of enrollees subject to SB 1021 currently have coverage for medications to prevent HIV/AIDS. CHBRP assumes health plans and policies are in compliance with the cost-sharing limits as introduced by AB 339.
3. **Utilization.** Because benefit coverage is 100%, CHBRP estimates there will be no change in utilization.
4. **Expenditures.** Because benefit coverage is 100%, CHBRP estimates there will be no change in expenditures.
5. **Medical effectiveness.**
 - a. Clear and convincing evidence that pre-exposure prophylaxis (PrEP) is effective at preventing HIV transmission.
 - b. Limited evidence that post-exposure prophylaxis (PEP) is effective at preventing HIV transmission.
 - c. Preponderance of evidence that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
6. **Public health.** SB 1021 would have no short-term public health impact.

7. Long-term impacts.

- a. Utilization of PrEP and PEP may increase if SB 1021 were to pass and awareness continues to increase among providers and consumers.
- b. The \$250 out-of-pocket cost-sharing limits are fixed; therefore, as drug costs increase, more drugs and enrollees will get closer to the out-of-pocket cost-sharing limit.

BILL SUMMARY

SB 1021 amends existing law put into place by the passage of AB 339 in 2015. AB 339 impacted the outpatient prescription drug coverage of Californians with health insurance regulated by DMHC or CDI, except Medi-Cal.¹

SB 1021 eliminates the sunset of January 1, 2020, for the provisions included in AB 339, extending this law indefinitely. Major provisions of AB 339 include:

- Copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed \$250.
- If a nongrandfathered individual or small-group market plan or policy maintains a drug formulary grouped into tiers that includes a fourth tier, specific definitions apply.

SB 1021 includes new provisions:

- Requires plans and policies to cover combination antiretroviral drug treatments that are medically necessary for the *prevention* of HIV/AIDS.
- Prohibits plans and policies from having more than four drug formulary tiers.
- Codifies existing DMHC regulation that states if a pharmacy's retail price for a prescription is less than the applicable copayment or coinsurance

¹ Refer to CHBRP's full report for full citations and references.

amount, the enrollee shall not be required to pay more than the retail price.

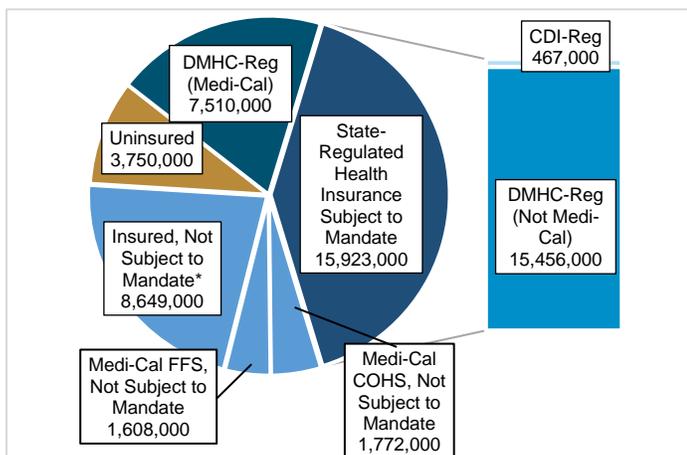
include copayments, coinsurance, and/or deductibles (but do not include premium payments).

A full list of all provisions included in SB 1021 is included in the *Policy Context* Section.

The provisions of SB 1021 apply to various numbers of Californians, dependent upon through which health insurance market a plan or policy is obtained.

Figure 1 notes the maximum number of Californians who have health insurance that would be subject to SB 1021.

Figure 1. Health Insurance in CA and SB 1021



Source: CHBRP 2018.
Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

CONTEXT

The analysis of SB 1021 is divided into two main sections: medications to prevent HIV/AIDS and cost-sharing provisions.

Two FDA-approved prescription drug regimens are relatively new additions to the public health prevention of HIV transmission strategies: pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). Both regimens are anti-retroviral treatments that prevent HIV from penetrating the CD4 cells. By protecting the cells, this regimen eliminates the ability of HIV to replicate and destroy the immune system.

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms

IMPACTS: MEDICATIONS TO PREVENT HIV/AIDS

Benefit Coverage, Utilization, and Cost

CHBRP found through a survey of the largest (by enrollment) providers of health insurance in California that 100% of enrollees subject to this provision of SB 1021 currently have coverage for preventive HIV/AIDS medications. Thus, there is no change in the benefit coverage of HIV/AIDS medications for prevention postmandate.

Utilization of PrEP and PEP would remain constant post-implementation. Similarly, expenditures would not be expected to increase since benefit coverage and utilization will not change.

Medi-Cal

Medi-Cal is exempt from the provisions of SB 1021.

CalPERS

No measurable impact is projected for enrollees who receive health insurance through CalPERS.

Number of Uninsured in California

No change in the number of uninsured persons is expected due to the enactment of SB 1021.

Medical Effectiveness

- There is clear and convincing evidence from 13 fair- and high-quality RCTs and three observational studies that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence.
- There is limited evidence from a single historical case-control study among hospital workers, low-quality observational studies, and animal studies

that PEP is effective in preventing HIV transmission following occupational and non-occupational exposures. Adherence and follow-up in PEP studies is overall low and therefore limits CHBRP's ability to draw conclusions about the relationship between adherence and effectiveness for PEP as well as the frequency of PEP failures.

- There is limited evidence (PrEP) or insufficient evidence (PEP) that health insurance coverage is effective in increasing use and adherence to preventive HIV/AIDS medications.

Public Health

CHBRP concludes that passage of SB 1021 would have no short-term public health impact because carriers report that 100% of enrollees currently have coverage for these benefits or that these provisions are required by current law; thus, no change in coverage or utilization would occur within the first 12 months of implementation.

Long-Term Impacts

Recent studies have reported that there is an upward trend in utilization of drugs for the prevention of HIV/AIDS. It is reasonable to assume that this increase in utilization would continue beyond the first 12 months of implementation of SB 1021 if it passes, as awareness continues to increase among providers and consumers.

IMPACTS: COST-SHARING PROVISIONS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

CHBRP assumes health plans and policies are in compliance with the cost-sharing limits as introduced by AB 339. While SB 1021 does not change the cost-sharing limits currently in law, given the increasing trend in drug prices, CHBRP assumes more enrollees will hit the cost-sharing limits over time assuming no other changes to the market.

Utilization

In its analysis of AB 339 in 2015, CHBRP estimated 0.8% of enrollees in plans and policies subject to AB 339 had outpatient prescription drug claims that would exceed the cost sharing limitations. CHBRP estimated a utilization increase of an additional 3,174 enrollees who previously did not use prescription drugs (increase of 2.43%) but who would with the passage of AB 339. Utilization is not projected to change should SB 1021 pass since this bill eliminates the sunset included in current law.

Medi-Cal

Medi-Cal is exempt from the provisions of SB 1021.

CalPERS

No measurable impact is projected for enrollees who receive health insurance through CalPERS.

Number of Uninsured in California

No change in the number of uninsured persons is expected due to the enactment of SB 1021.

Medical Effectiveness

- There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
- There is a preponderance of evidence from studies with moderate research designs that poorer adherence to prescription drugs therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.

Public Health

CHBRP concludes that passage of SB 1021 would have no short-term public health impact because carriers report that 100% of enrollees currently have coverage for these benefits or these provisions are required by current law;

thus, no change in coverage or utilization would occur within the first 12 months of implementation.

Long-Term Impacts

The \$250 out-of-pocket cost-sharing limits are fixed; therefore, as drug costs increase, more drugs and enrollees will get closer to the out-of-pocket cost-sharing limit. CHBRP completed a 3-year projection of the number of enrollees hitting the cost-sharing limit of \$250 per prescription for up to a 30-day supply, assuming all else remains constant (i.e., number of approved drugs and utilization and formulary structure).

Table 1. Maximum Projected Share of Enrollees Who Hit the Cost-Sharing Limit as Included in SB 1021

Year	Maximum projected number (#) of enrollees who hit cost-sharing limit	Maximum projected percent (%) of enrollees who hit the cost-sharing limit
2019	834,500	5.24%
2020	967,700	6.08%
2021	1,097,100	6.89%

Source: California Health Benefits Review Program, 2018.
Note: Based on MarketScan claims database sample data.

ESSENTIAL HEALTH BENEFITS AND THE AFFORDABLE CARE ACT

SB 1021 would require coverage for preventive HIV/AIDS medications and specifies terms of outpatient prescription drug coverage, and therefore appears not to exceed the definition of EHBs in California.

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California Health Benefits Review Program

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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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POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)² conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 1021, Prescription Drugs.

Bill-Specific Analysis of SB 1021, Prescription Drugs

Bill Language

SB 1021 amends existing law put into place by the passage of Assembly Bill (AB) 339 in 2015. AB 339 impacted the outpatient prescription drug coverage of Californians with health insurance regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI), except Medi-Cal. Major provisions of AB 339, as enacted, require:

- Copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed \$250.
 - With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription supply of up to 30 days shall not exceed \$500.
 - For high-deductible health plans (HDHPs), this provision shall only apply once an enrollee's deductible is met.
- If a nongrandfathered individual or small-group market plan or policy maintains a drug formulary grouped into tiers that includes a fourth tier, specific definitions apply.
- All provisions above shall remain in effect only until January 1, 2020.

SB 1021 eliminates the sunset for the provisions included in AB 339, extending this law indefinitely. Table 1 compares the provisions included in current law with SB 1021 and also provides the market segment and population impacted by the specific provision.

² CHBRP's authorizing statute is available at <http://chbrp.org/faqs.php>.

Table 1. Comparison of Provisions in AB 339 and SB 1021 and Market Segment and Population Impacted by SB 1021.

Provision	AB 339	SB 1021	Market and Number of Enrollees with Health Insurance Subject to SB 1021
HIV/AIDS Medications	Requires plans and policies to cover combination antiretroviral drug treatments that are medically necessary for <i>the treatment</i> of HIV/AIDS. Plans/policies must cover a single-tablet drug regimen that is as effective as or more effective than multitablet regimens.	SB 1021 extends AB 339 to require plans and policies to cover combination antiretroviral drug treatments that are medically necessary for the treatment and prevention of HIV/AIDS. Plans/policies must cover a single-tablet drug regimen that is as effective as or more effective than multitablet regimens.	DMHC- and CDI-regulated plans and policies, except Medi-Cal, and specialized health plans = 15.9 million enrollees
Enrollee Out-of-Pocket Cost-Sharing Limitations for OPDs	<p>a. Limits cost sharing of covered outpatient prescription drugs to \$250 per individual prescription supply of up to 30 days.</p> <p>b. For products with actuarial value at or equivalent to bronze level, limits cost sharing of outpatient prescription drugs to \$500 per individual prescription supply of up to 30 days.</p> <p><i>These provisions apply to enrollees with high-deductible health plans once the deductible is met.</i></p>	Same as AB 339	DMHC- and CDI-regulated plans and policies, except Medi-Cal, and specialized health plans = 15.9 million enrollees
Allowed Deductible for OPD Benefits	<p>The annual deductible for outpatient prescription drugs, if any, shall not exceed twice the amount specified above, respectively.</p> <p><i>This provision applies to enrollees with high-deductible health plans once the deductible is met.</i></p>	Same as AB 339	DMHC- and CDI-regulated nongrandfathered plans and policies in the individual and small-group markets = 4.9 million enrollees

Provision	AB 339	SB 1021	Market and Number of Enrollees with Health Insurance Subject to SB 1021
Definition of Formulary Tiers	If a plan or policy offers an OPD benefit with a fourth tier, tiers must be defined per existing law.	Same as AB 339	DMHC- and CDI-regulated plans and policies in the individual and small-group markets = 5.45 million enrollees
OPD Formulary Tiers	<p>a. A plan or policy may maintain a drug formulary with fewer than four tiers.</p> <p>b. A plan or policy shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.</p>	<p>SB 1021 extends this provision to include the following:</p> <p>a. Prohibits plans and policies from having more than four drug formulary tiers.</p> <p>b. Allows plans and policies to place biologic therapeutics equivalents on tiers lower than level 4.</p>	DMHC- and CDI-regulated plans and policies in the individual and small-group markets = 5.45 million enrollees
Retail Price of Prescriptions	None	Codifies existing DMHC regulation that states if a pharmacy’s retail price for a prescription is less than the applicable copayment or coinsurance amount, the enrollee shall not be required to pay more than the retail price.	DMHC- and CDI-regulated plans and policies, except Medi-Cal, and specialized health plans = 15.9 million enrollees

Source: California Health Benefits Review Program, 2018.

Key: DMHC= Department of Managed Health Care; CDI= California Department of Insurance; OPD= Outpatient Prescription Drugs.

The full text of SB 1021 can be found in Appendix A .

Relevant Populations

Californians with health insurance regulated by DMHC or CDI may be subject to state health benefit mandate laws. If enacted, SB 1021 would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, including CalPERS, and exempting Medi-Cal Managed Care Plans regulated by DMHC and plans and policies that do not provide outpatient prescription drug coverage. Additional detail is included above in Table 1.

If enacted, most of SB 1021’s provisions would affect the health insurance of approximately 15.9 million enrollees (41% of all Californians). This represents 68% percent of the 23.4 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate in 2019.

As indicated in Table 1, only enrollees with DMHC- or CDI-regulated plans or policies in the individual and small-group markets are subject to the *OPD Formulary Tiers and Definitions of Formulary Tiers* provisions. This provision would affect the health insurance of approximately 5.45 million enrollees (14% of all Californians). This represents 23% of the 23.4 million Californians who will have health insurance regulated by the state in 2019. The provision that limits the *Allowed Deductible for OPD Benefits* applies only to the 4.9 million enrollees in DMHC- and CDI-regulated nongrandfathered plans and policies in the individual and small group markets (12% of all Californians). This represents 20% of the 23.4 million Californians who will have health insurance regulated by the state in 2019.

As further discussed in Appendix E, approximately 1.4% of enrollees in DMHC-regulated plans and CDI-regulated policies have no coverage for outpatient prescription drugs (OPDs) and 3.0% have OPD coverage that is not regulated by DMHC or CDI. These enrollees have health insurance that is considered to be compliant with SB 1021 and so CHBRP has projected no mandate impacts related to enrollees without a DMHC- or CDI-regulated OPD benefit.

Analytic Approach and Key Assumptions

CHBRP conducted an analysis on similar legislation, AB 339³, introduced during the 2015-2016 Legislation Session. AB 339 was amended and signed into law on October 8, 2015.⁴ The analysis of SB 1021 builds on the previous report.

- CHBRP assumes 100% of enrollees have health insurance fully compliant with AB 339, and therefore CHBRP does not analyze the impact of the provisions included in the initial legislation. Where available we have included information from the previous report.
- CHBRP analyzed the impacts of the Allowed Deductible for OPD Benefits and the Definition of Formulary Tiers in the analysis of AB 339. Information about these provisions is presented within this report analyzing SB 1021.
- AB 339 was not fully implemented until January 1, 2017, and therefore data about the impact of AB 339 is not available within commercial MarketScan claims data used by CHBRP to estimate the impact of proposed legislation. Covered California implemented the provisions of AB 339 for the individual market in 2015 through the Standard Plan Benefit Design.⁵
- SB 1021 does not impact utilization management techniques plans and policies may use, such as prior authorization or step-therapy.
- CHBRP does not analyze the impact of cost-sharing assistance programs provided to enrollees because they are not systematic or permanent and are not included in claims data. Examples include a pharmaceutical manufacturer's coupon, private cost-sharing assistance programs, or statewide assistance programs developed by state agencies.

³ CHBRP's analysis of AB 339 is available at: http://chbrp.org/completed_analyses/index.php

⁴ Final text of AB 339 is available at:

http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB339

⁵ California Health Benefit Exchange Board. Meeting Minutes from May 21, 2015. Available at: <http://board.coveredca.com/meetings/2015/6-18/May%2021%202015%20Minutes%20FINAL.pdf>

Report Layout

CHBRP has focused on three provisions within this report: Medications to Prevent HIV/AIDS, Enrollee Out-of-Pocket Cost-Sharing Limitations, and Outpatient Prescription Drug Formulary Tiers. Headers as indicated in Table 1 will be used to refer to specific pieces of the legislation.

- “Medications to Prevent HIV/AIDS” refers to the provision of SB 1021 that requires plans and policies to cover *preventive* HIV/AIDS medications, as specified above. This provision is newly added by SB 1021.
- “Cost-Sharing Provisions” refers to two components of the bill:
 - “Enrollee Out-of-Pocket Cost-Sharing Limitations for OPDs” refers to the provisions that place cost-sharing limitations of \$250 or \$500 per individual prescription for up to a 30-day supply. While this provision was included with the passage of AB 339, CHBRP has provided an update to information included in its analysis of AB 339 as well as information on the impact of these cost-sharing limitations.
 - “Outpatient Prescription Drug Formulary Tiers” refers to the provision that limits DMHC- and CDI-regulated nongrandfathered plans and policies in the individual and small-group markets to four tiers. This provision is newly added by SB 1021.

Provisions discussed briefly within CHBRP’s report of SB 1021 are:

Medications to Treat HIV/AIDS

- This provision requires that plans and policies cover combination antiretroviral drug treatments that are medically necessary for the treatment of HIV/AIDS. Plans/policies must cover a single-tablet drug regimen that is as effective as or more effective than multitablet regimens.
- CHBRP presented a case study on OPD coverage of HIV/AIDS medications within the analysis of AB 339. This case study includes a background on HIV/AIDS, medications, insurance coverage, placement on formulary tiers, and implications based on the enactment of AB 339 as analyzed. The full report is available on CHBRP’s website.⁶

Allowed Deductible for OPD Benefits

- This provision applies to a subset of enrollees subject to SB 1021, only those enrolled in DMHC- and CDI-regulated nongrandfathered plans and policies in the individual and small-group markets, and limits the allowed deductible to twice the Enrollee Out-Of-Pocket Cost-Sharing Limitation.
- This provision was enacted through the passage of AB 339 and the corresponding sunset will be eliminated should SB 1021 be enacted. Information about deductibles is included in the *Background on Medications to Prevent HIV/AIDS and on Cost Sharing for Prescription Drugs* section. Because SB 1021 is not amending this provision, CHBRP did not analyze the impacts within the report on SB 1021.

⁶ CHBRP’s analysis of AB 339 can be found at: <http://analyses.chbrp.com/document/view.php?id=1027>

Outpatient Prescription Drug Formulary Tiers

Four provisions impacting OPD Formulary Tiers are included in SB 1021.

- Two provisions remain unchanged from AB 339 and are not discussed within this report:
 - A plan or policy may maintain a drug formulary with fewer than four tiers.
 - A plan or policy shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.
- Two provisions are newly added through SB 1021:
 - Prohibits plans and policies from having more than four drug formulary tiers. This provision is discussed throughout SB 1021.
 - Allows plans and policies to place biologic therapeutics equivalents on tiers lower than level 4. This provision does not compel plans and policies to take action and CHBRP does not estimate how or whether insurers may change the tier a drug is placed within.

Retail Price of Prescriptions

- SB 1021 codifies existing DMHC regulation that states if a pharmacy's retail price for a prescription is less than the applicable copayment or coinsurance amount, the enrollee shall not be required to pay more than the retail price. CDI-regulated policies would also be subject to this regulation should SB 1021 pass into law. This provision is discussed within the *Background on Medications to Prevent HIV/AIDS and on Cost Sharing for Prescription Drugs* section, as well as the *Benefit Coverage, Utilization, and Cost Impacts* section. Although a literature review was not performed on this topic, recent studies have been included in the *Background* discussion.

Interaction with Existing Requirements

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

California Policy Landscape

California law and regulations

CDI indirectly limits expenses paid by the insured, requiring all policies to be economically sound,⁷ and requires that individual policies provide “real economic value” to the insured.⁸ Further, CDI requires the coverage of all medically necessary prescription drugs.

DMHC-regulated plans are subject to statutory and regulatory requirements regarding coverage of outpatient prescription drugs.⁹ DMHC-regulated plans are required to:

⁷ IC Section 10291.5(a)(1).

⁸ IC Section 10291.5(b)(7)(A) and 10270.95.

⁹ H&SC Sections 1342.7 and 1367; California Code of Regulations Section 1300.67.24.

- Cover medically necessary prescription drugs, and to ensure access to these medically necessary prescription drugs by establishing reasonable cost sharing.
- Set limits and exclusions on outpatient prescription drug coverage that are consistent with current evidence-based outcomes and peer-reviewed medical and pharmaceutical literature.

In addition, when reviewing cost sharing on outpatient prescription drugs, DMHC will base approval or disapproval of proposed cost-sharing structures on the availability of therapeutic equivalents and the effect on affordability of, and access to, coverage, among other factors. It is important to note that California's essential health benefits (EHBs) in compliance with the Affordable Care Act (discussed further below), are based on a DMHC-regulated plan. Therefore, nongrandfathered small-group and individual market CDI-regulated policies that are required to cover EHBs are also subject to these DMHC-regulated requirements on outpatient prescription drug coverage.

Covered California

Covered California's 2016 Standard Benefit Plan Design:¹⁰

- Limits insurance companies offering health insurance plans and policies through the marketplace to four drug formulary tiers.¹¹
- Specifies individual and family deductibles and out-of-pocket maximums based on the metal level and plan type.

The Board of Covered California voted to make adjustments to the prescription drug coverage benefit within the health insurance marketplace in 2016, including establishing requirements for access to chronic care drugs across prescription drug tiers. As of 2016, qualified health plans (QHPs)¹² sold in Covered California meet the following requirement:

- If a drug would otherwise qualify for placement on tier 4 and at least three treatment options are available for that particular condition as determined by either a plan's pharmaceutical and therapeutics (P&T) committee or indicated by the Food and Drug Administration (FDA) or according to applicable treatment guidelines for that condition, at least one drug for that condition must be placed on either prescription drug tier 1, 2, or 3.¹³

Similar requirements in other states

CHBRP is unaware of other states that mandate coverage for preventive HIV/AIDS medications.

At least five other states limit enrollee out-of-pocket cost sharing for outpatient prescription drugs (Ludec, 2016). Three states (Delaware, Louisiana, and Maryland) limit the amount an enrollee pays per individual prescription supply for up to 30 days for specialty-tier drugs. Maine and Vermont impose an annual limitation on an enrollee's out-of-pocket expenses for outpatient prescription drugs.

¹⁰ Covered California's 2016 Standard Benefit Plan Design available at:

http://hbex.coveredca.com/regulations/PDFs/2016%20Standard%20Benefit%20Plan%20Design_Second%20Readopt%2005%2021%2015_OAL%20approved_CLEAN.pdf

¹¹ More information about Formulary Tiers is included in the *Background* section.

¹² In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's health insurance marketplace.

¹³ Covered California Board Meeting March 5, 2015, Covered California Policy and Actions Items, available at:

http://board.coveredca.com/meetings/2015/3-15/PPT%20-Covered%20California%20Policy%20and%20Action%20Items_March%205,%202015.pdf.

At least six states (AZ, CO, NH, NY, VA, and WY) introduced legislation in 2018 that prohibits pharmacists from charging enrollees an amount that exceeds the retail price of a prescription.¹⁴ Additionally, at least 20 states (AZ, FL, KS, MD, MO, MS, NE, NH, NJ, NY, PA, SC, SD, UT, VA, VT, WA, WI, WV, and WY) introduced legislation in 2018 that would prohibit pharmacy benefit managers (PBMs) or insurers from prohibiting a pharmacy or pharmacist from providing an enrollee information about more affordable alternative medications if available or requires pharmacists to inform enrollees of lower cost alternatives.^{15,16} Connecticut, Georgia, and North Carolina passed similar legislation in 2017.¹⁷

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 1021 may interact with requirements of the ACA as it presently exists in federal law, including the requirement for certain health insurance to cover EHBs.¹⁸

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

The ACA requires that all health insurance plans offered in the small-group and individual markets provide a comprehensive package of benefits in 10 categories. The 10 categories include preventive and wellness services, chronic disease management, as well as prescription drugs.

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{19,20} The benchmark plan includes coverage for "anti-HIV Agents."

SB 1021 would require coverage for preventive HIV/AIDS medications and specifies terms of outpatient prescription drug coverage, and therefore appears not to exceed the definition of EHBs in California.

¹⁴ National Academy for State Health Policy (2018). State Prescription Drug Legislative Tracker 2018. Available at: <https://nashp.org/wp-content/uploads/2018/01/StateRXTrackerFinal22318.pdf>

¹⁵ State of Arizona, House Bill 2107. Available at: <https://apps.azleg.gov/BillStatus/GetDocumentPdf/458810>

¹⁶ National Academy for State Health Policy (2018). State Prescription Drug Legislative Tracker 2018. Available at: <https://nashp.org/wp-content/uploads/2018/01/StateRXTrackerFinal22318.pdf>

¹⁷ National Academy for State Health Policy (2017). State Prescription Drug Legislative Tracker 2017. Available at: <https://nashp.org/wp-content/uploads/2016/09/Rx-Legislative-Tracker-2017-Final.pdf>

¹⁸ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

¹⁹ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

²⁰ H&SC Section 1367.005; IC Section 10112.27.

BACKGROUND ON MEDICATIONS TO PREVENT HIV/AIDS AND ON COST SHARING FOR PRESCRIPTION DRUGS

SB 1021 addresses two distinct subjects: coverage of medications that prevent HIV infection and an extension of existing limitations on cost-sharing for outpatient prescription drugs. This background section provides contextual information for the consideration of the medical effectiveness, cost and utilization, and public health impacts of both subjects.

Human Immunodeficiency Virus (HIV)

Human immunodeficiency virus (HIV) attacks the body's CD4 cells (one type of white blood cell known as T cells), which are integral to the body's immune function. Left untreated, opportunistic infections including infection-related cancers, will eventually compromise the health of an individual and lead to death. HIV invades and effectively destroys CD4 cells during the virus replication process. The acute HIV infection stage (within the first two to four weeks of exposure where flu-like symptoms may occur) is a highly contagious stage because of a large amount of virus in the body. This is followed by a latent/asymptomatic period (lasting up to 10 years if untreated) where the virus replicates at a significantly slower rate; however, the individual remains contagious. Acquired immune deficiency syndrome (AIDS) is the most serious stage of HIV infection where the body's immune system is severely compromised with a CD4 count below 200 cells/mm and is highly contagious (HHS, 2017).

There is no cure for HIV/AIDS; however, lifelong, highly active anti-retroviral therapy (HAART) stops the disease progression by reducing the viral load in the blood stream and enables individuals to maintain a functional immune system. Due to the effectiveness of HAART treatments, people living with HIV now achieve a life expectancy similar to that of the general population (Antiretroviral Therapy Cohort Collaboration, 2017).

Medications to Prevent HIV/AIDS

What Are Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)?

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. Two therapeutic strategies are relatively new additions to the public health prevention toolbox (e.g., education, needle exchanges, and condom programs): pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). Both strategies involve using anti-retroviral medications that prevent HIV from penetrating the CD4 cells. 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 HAART for people living with HIV. (See Table 2 for summary comparison and Appendix B for more detail regarding alternative therapies.)

PrEP

PrEP is a long-term regimen recommended for the population that has repeated, intimate exposure to HIV-positive individuals or other high-risk individuals of unknown HIV status. The only FDA-approved PrEP therapy is a single tablet combination therapy of tenofovir disoproxil fumarate and emtricitabine (brand name: Truvada®), which was approved by the FDA in 2012. PrEP users take a single tablet once per day as long as they remain in circumstances where HIV exposure is likely to occur. PrEP is indicated

for specific groups practicing high-risk behaviors, including a subset of men-who-have-sex-with-men (MSM)²¹, a subset of heterosexually active men and women²², and injection drug users²³ (USPHS, 2014). Providers may prescribe only tenofovir disoproxil fumarate for certain subpopulations with drug-drug contraindications (e.g., women taking oral contraceptives, or injection drug users on medication-assisted therapy).

Practice guidelines for PrEP, issued by the U.S. Public Health Service in 2014, recommend that providers perform an HIV risk-behavior assessment using approved questions, and prescribe a PrEP regimen for those patients at high risk for HIV.

PEP

PEP is a short-term, daily therapy similar to that of PrEP. However, this regimen must be started within 72 hours of (suspected) HIV exposure and is only taken for 28 days. In combination with the single tablet, Truvada®, adult patients also take another drug such as raltegravir (twice) or dolutgravir (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), newborns to HIV positive mothers, MSM, and injection drug users. PEP is not recommended for HIV-negative individuals practicing high-risk behaviors; frequent PEP treatment may increase an individual's resistance to HAART, thus making the management of HIV more difficult should they seroconvert (CDC, 2017b). See Table 2 for a summary comparison of PrEP and PEP.

There are several national clinical practice guidelines for PEP, in addition to the 2013 World Health Organization guidelines (WHO, 2013). In the U.S., the Centers for Disease Control and Prevention issued PEP guidelines for non-occupational exposure (nPEP) and the U.S. Public Health Service issued guidelines for occupational exposure (oPEP) (CDC, 2016; Kuhar et al., 2013). Each guideline recommends a different HIV-risk assessment tool (e.g., healthcare workers are at lower risk for contracting HIV from an occupational needle stick than a newborn whose mother is HIV positive). However, once risk is deemed high enough for treatment (according to exposure status), the recommended PEP treatments are the same for occupational and non-occupational exposures (CDC, 2016). The body of literature is more comprehensive for PrEP than PEP. CHBRP presents evidence regarding PEP when available; however, not every section in this report will present PEP information in parallel with PrEP (i.e., disparities in use or provider prescribing).

²¹ Subset of MSM recommended to use PrEP includes adult men, without acute or HIV-established infection, with male sex partners in past 6 months, not in a monogamous partnership with a HIV-negative man, AND at least one of the following: any anal sex without condoms, or STI diagnosed in past 6 months, or is in an on-going sexual relationship with an HIV-positive male partner (USPHS, 2014).

²² Adult without acute or HIV-established infection, any sex with opposite sex partners in the past 6 months, not in a monogamous partnership with recently tested HIV-negative partner, AND at least one of the following: a man who is behaviorally bisexual, infrequently uses condoms during sex with 1 more partners if unknown HIV status who are injection drug users or bisexual male partner, or is in an ongoing relationship with an HIV-positive partner.

²³ Adult without acute or HIV established infection, any injection of drugs not prescribed by a clinician in past 6 months AND at least one of the following: any sharing of injection drug equipment in past 6 months; been in a methadone, buprenorphine, or suboxone treatment program in the last 6 months; or risk of sexual acquisition.

Table 2. Summary of PrEP and PEP Regimens for the Prevention of HIV Infection

HIV Pre-Exposure Prophylaxis (PrEP)	HIV Post-Exposure Prophylaxis (PEP)
<p>Reasons for Initiation</p> <p>PrEP is recommended for seronegative persons, before possible exposure, who think they may have repeated exposure to HIV. Examples of situations meeting this standard include for protection of HIV-negative partner in serodiscordant couples; MSM with multiple partners, sex workers, and injection drug users (IDU).</p>	<p>Reasons for Initiation</p> <p>CDC recommends using PEP only in emergency situations if HIV exposure is suspected. Examples of events meeting this standard include sexual intercourse or shared use of drug equipment with a (suspected) HIV-positive person, newborns born to HIV-positive mothers, cases of sexual assault, condom failure, or occupational transmission to healthcare workers.</p>
<p>Preferred Regimens</p> <ul style="list-style-type: none"> Preferred regimen is a combination therapy in a single pill (tenofovir disoproxil fumarate, and emtricitabine (Truvada®) taken once daily for as long as the patient has intimate exposure to HIV-positive individuals. 	<p>Preferred Regimens</p> <ul style="list-style-type: none"> <u>For adults:</u> Truvada® (once daily) with raltegravir (twice daily) or dolutegravir (once daily) as, initiated within 72 hours of suspected exposure and continued for 28-days. <u>Newborns:</u> Zidovudine for 4 weeks (low risk) or zidovudine and lamivudine for 6 weeks (high risk with untreated HIV-positive mother) initiated as close to birth as possible (6-12 hours).
<p>Concurrent Care Recommended</p> <p>Baseline HIV test; quarterly blood panels for Truvada® refill authorization, pregnancy test, HIV test or risk assessment, and adherence; blood tests every 6 months for renal/hepatic effects and STI tests; annual appointments to evaluate effectiveness and adherence to therapy protocol.</p>	<p>Concurrent Care Recommended</p> <p>Baseline HIV test; follow-up appointment with HIV test; counseling on risk behavior reduction.</p>
<p>Effectiveness</p> <p>With proper PrEP adherence, risk of HIV infection may be reduced by 92% for MSM, 90% for heterosexual men and women, and by 70% for IDU.</p>	<p>Effectiveness</p> <p>Most effective when initiated as close to exposure as possible. Not effective if started after 72 hours of exposure.</p>

Source: California Health Benefits Review Program, 2018, based on CDC, 2017b; USPHS, 2014; and PTPWPPT, 2018.

Key: IDU = Injection drug users; STI = sexually transmitted infection.

Population at Risk for HIV in California

Because SB 1021 would amend current law to require coverage of prophylaxis therapy for HIV, the population of interest for this provision is the pool of Californians that meet the Centers for Disease Control and Prevention’s indications for PrEP and PEP (CDPH, 2016). In particular, MSM, transgender women, African Americans, Latinos and injection drug users have the highest prevalence of HIV, and continue to be at highest risk for contracting HIV.

PrEP Population

The California Department of Public Health, Office of AIDS, estimated that between 221,528 and 238,628 Californians would meet the criteria for PrEP (CDPH, 2016), which is about double the prevalence of people living with HIV in California (128,415 in 2015) (CDPH, 2017a). The incidence of HIV (newly

diagnosed cases) has remained close to 5,000 cases per year (of which 88% are male) since 2011 (CDPH, 2017a). See Table 3 for estimates of Californians at risk of HIV infection who would be candidates for PrEP. Note that the insurance status of this population is unknown; it includes the subset of at-risk persons with insurance subject to SB 1021.

Table 3. Estimated Number of Californians at High Risk of HIV Infection in California, 2015

Population	Estimated number of Californians with indication for PrEP
MSM	103,779 – 120,879
High-risk heterosexuals	105,541
Injection drug users	12,208
TOTAL	221,528 – 238,628

Source: California Health Benefits Review Program, 2018 based on CDPH, 2017a.

Note: Insurance status of this population is unknown; it may include Medi-Cal, privately insured, uninsured, Medicare, and other forms of insurance.

Key: MSM = men who have sex with men; PrEP = pre-exposure prophylaxis.

PEP Population

CHBRP was unable to find an estimate of the California population at risk of requiring PEP. Identifying the population that meets the PEP criteria is challenging to the public health community since, by definition, the exposures are periodic, emergency-based, and dispersed among a disparate population. Additionally, determining patient PEP uptake and adherence is challenging due to PEP initiation potentially occurring in different settings than follow-up visits (i.e., emergency department, or free clinic followed by a private physician visit). Frequently there is a lack of patient follow-up to confirm PEP adherence or for confirmatory HIV testing (Ford et al., 2014).

Provider Awareness of and Willingness to Prescribe PrEP

Provider awareness of and willingness to prescribe PrEP is equally important to patient uptake of the regimen (Tuller, 2018). A 2015 survey of 1,501 U.S. clinicians (36% family/general practitioners, 31% internists, 17% nurse practitioners, and 17% obstetrician/gynecologists) found that 22% of clinicians had read the CDC guidelines for PrEP and that 79% were willing to prescribe PrEP to a negative partner in an HIV discordant couple (61% for couples planning to conceive); 66% were willing to prescribe for MSM; 63% for injection drug users, and 34% for patients diagnosed with a sexually transmitted infection (STI). The participating clinicians had limited knowledge of PrEP with more than 50% of true/false questions receiving an incorrect or “don’t know” response (Smith et al., 2016).

To improve provider awareness and willingness to prescribe PrEP, the California Department of Public Health, Office of AIDS, is using funding from the Centers for Disease Control and Prevention to provide PrEP education, training, and technical assistance to California providers with the goal of increasing MSM and transgender individual’s uptake of PrEP. The Office of AIDS also uses federal dollars to fund two other outreach programs — the Strategic HIV Prevention Program and the PrEP Navigator Project — which educate and motivate populations at high risk for HIV to adopt PrEP (CDPH, 2017b).

Disparities²⁴ and Social Determinants of Health²⁵ in Prevention of HIV/AIDS

Disparities

Racial/ethnic disparities

The CDC’s 2018 analysis of U.S. PrEP prescriptions, prevalence of high-risk behaviors, and HIV prevalence found disparities between African American and Latino uptake rates as compared with uptake rates of whites (CDC, 2018). They estimated that 500,000 African Americans and almost 300,000 Latinos were eligible for PrEP based on CDC clinical guidelines, but 7,000 and 7,600 PrEP prescriptions were filled, respectively, at retail/mail order pharmacies (Smith et al., 2018). Whites experienced a similar unmet need, although the gap was smaller with 42,000 PrEP prescriptions filled among 300,000 whites who met the CDC guidelines. Limitations to the study included no documentation of insurance status and no ascertainment of patient assistance programs used, or prescriptions filled through military health systems or closed managed care systems.

Figure 1. Estimated Number of Adults who could Potentially Benefit from PrEP, United States, 2015

	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
Total who could potentially benefit from PrEP	813,970	258,080	72,510	1,144,550

Notes: PrEP=pre-exposure prophylaxis; data for “other race/ethnicity” are not shown



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Source: CDC, 2018.

California’s racial/ethnic disparities in use of PrEP is similar to those reported at the national level. Although SB 1021 exempts Medi-Cal from covering PrEP, this recent study by Harawa et al. (2018) demonstrates disparities that might also occur among Californians with private coverage. It finds that

²⁴ 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.

²⁵ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP’s SDoH white paper for further information: http://www.chbrp.org/analysis_methodology/docs/Incorporating_Relevant_Social_Determinants_of_Health_in_CHBRP_Analyses_Final_to_WEBSITE_033016.pdf.

although PrEP uptake by Medi-Cal users was 25 times greater in 2016 than in 2012 (9 per million Medi-Cal enrollees in 2012 to 228 per million in 2016), the uptake rate among races was varied, with some groups at higher risk having lower uptake rates. For example, the disparity between black/African American and white Medi-Cal beneficiaries' uptake widened between 2013 and 2016; black/African American uptake increased from 14.6 per million to 282 per million while white uptake increased from 16.6 million to 447 per million. The greatest rate increase occurred among Hispanics (who also experience a disproportionate share of HIV infection), but they still had the lowest utilization rate (106 per million) in 2016. Uptake rates for Asian and "other" Medi-Cal beneficiaries were 229 per million and 306 per million, respectively. This racial/ethnic disparity is present in the general population as well with African Americans representing 44% of new HIV infections but 13% of PrEP users; similarly, Latinos represented 24% of new infections but 18% of PrEP users while whites accounted for 25% of new HIV diagnoses but 62% of PrEP users (Tuller, 2018). CHBRP found no studies identifying racial/ethnic disparities in PEP use across the population.

Sexual orientation/identity

Of the subpopulations at highest risk for HIV, MSM and transgender women (male-to-female) experience high rates of HIV. CDC reports that 28% of transgender women in the U.S. test positive for HIV (CDC, 2017c). MSM represent about 2% of the U.S. population, but accounted for 61% of new HIV infections in 2009 (CDC, 2017c). Both groups also have been found to have among the lowest rates of PrEP initiation and continuation. For example, 761 young California MSM (aged 18-29 years) using geosocial apps were surveyed about their use of PrEP. Fewer than 10% reported ever taking PrEP and, of those who reported ever taking PrEP, 72% reported currently taking PrEP. CHBRP found no studies identifying disparities in PEP by sexual orientation.

Social Determinants of Health

Two primary social determinants of health associated with the use of PrEP relate to geographic location and stigma:

Geography: A small qualitative study sponsored by the California HIV/AIDS Research Centers reported interview results from rural county PrEP navigators and AIDS Drug Assistance Program (ADAP) enrollment workers. These frontline workers reported that very few providers are educated about or willing to provide PrEP in their locales, thus PrEP users have to travel longer distances to receive care. Informants believed this barrier reduced PrEP initiation and continuation (Fuller et al., 2018). The Harawa et al. (2018) study reported that the disparity in uptake between Medi-Cal rural and urban beneficiaries; rural uptake was 104 per million beneficiaries and urban uptake was 2.5 times greater (253 per million) in 2016.

Stigma: Many PrEP-eligible patients report stigma as a significant barrier to initiating and maintaining PrEP use. Some with private insurance seek care through public clinics to avoid (perceived) judgement by their private primary care provider, yet the clinics re-refer them to the private provider. The aforementioned Fuller et al. (2018) study found that frontline PrEP workers expressed concern that these privately-insured individuals denied treatment from the clinic would not initiate PrEP with their private provider. Similarly, the frontline PrEP workers observed that individuals with high-deductible health insurance or higher incomes are ineligible for patient assistance programs, which was also perceived as a barrier to prompt and consistent PrEP use (Fuller et al., 2018).

Societal Burden of HIV

See the *Long-Term Impacts* section for discussion of cost-effectiveness of HIV prevention therapies.

Cost Sharing and Outpatient Prescription Drug Benefits

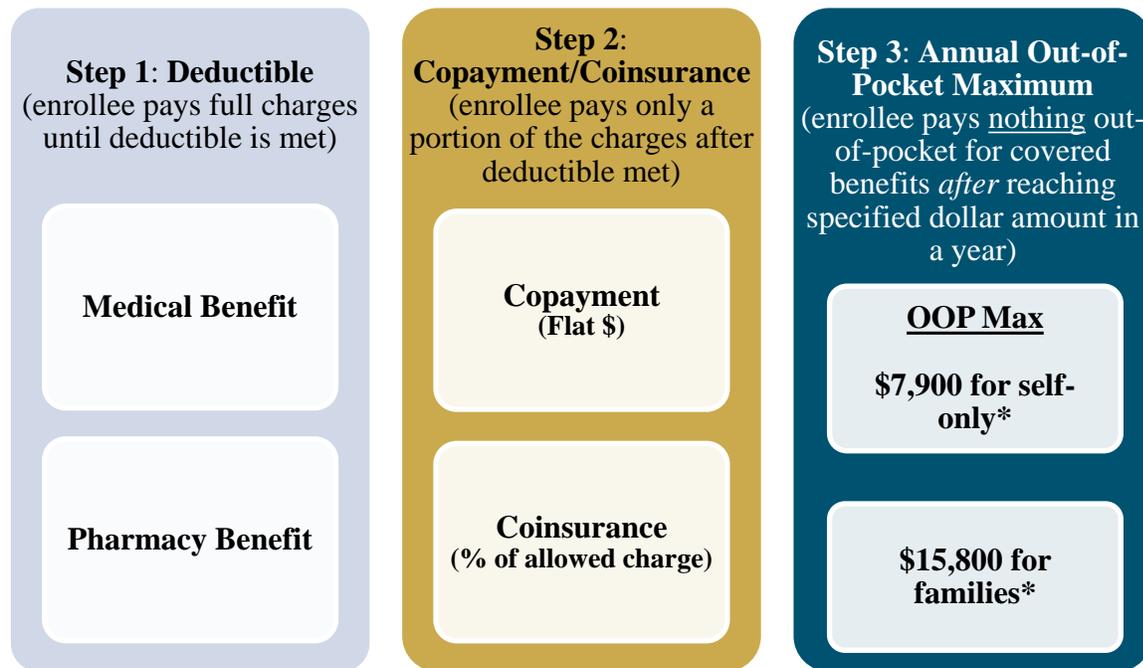
This section provides an overview of the cost-sharing and utilization management structures used for health insurance benefits, including prescription drugs. Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these collectively as enrollee out-of-pocket expenses.²⁶ There are a variety of cost-sharing mechanisms employed by insurance carriers to manage the cost of health care and ensure medically necessary care (Figure 2). SB 1021 would extend a California law²⁷ that limits cost sharing for outpatient prescription drugs to no more than \$250 per 30-day supply per prescription; it also would limit the number of tiers on formularies for plans in the individual and small-group markets.

As a reminder, annual out-of-pocket maximums are limits on the enrollee's cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. After the amount an enrollee has paid for copayments, coinsurance, and deductibles reaches this limit, insurance pays 100% of the cost of covered care. Health care services that are not covered by the health plan or insurer would not be included in the maximum; enrollees are responsible for the full charges associated with noncovered services.

²⁶ See CHBRP's Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

²⁷ H&SC 1342.71 and IC 10123.193

Figure 2. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2018.

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 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 amounts in this figure are the HHS proposed maximum amounts allowed in 2019 (Klinger, 2017); some plans and policies may have lower annual out-of-pocket maximums.

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

Outpatient Prescription Formulary Tier Structures

In general, outpatient prescription drug benefit designs can be characterized by the number of tiers into which the drugs are divided, each tier having a distinct cost-sharing level. The prescription drugs in the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some health plans or insurers use a four-tier (or higher) system that generally includes life-style drugs (e.g., infertility, erectile dysfunction, weight loss) and specialty drugs (i.e., biological agents treating rheumatoid arthritis or multiple sclerosis); typically, these are the most expensive drugs. Regardless of the tier structure, California law currently limits the enrollee cost of a 30-day supply per prescription to \$250.

Average Copayment/Coinsurance by Tier Level in California

The California Employer Health Benefits Survey found that the average copayment per prescription among California workers in 2016 was \$11.93 for generics, \$32.05 for preferred, and \$52.79 for nonpreferred drugs (CHCF, 2017), meaning that a preferred drug copayment is, on average, about 60% of a nonpreferred drug copayment for California enrollees with an employer-sponsored plan.

Distribution of Prescription Drugs by Tiers in California

Overall, it appears that insured Californians have less exposure to the highest levels of cost sharing for outpatient prescription drugs than their counterparts in other states. Table 4 shows the frequency of different prescription drug benefit structures among employer-sponsored health insurance in California and nationally. The proportion of workers in a four-tier cost-sharing structure increased in California from 2% in 2008 to 15% in 2014 and to 22% in 2016. Nationally, there was a statistically significant increase in the percent of workers shifting to a four-tier structure between 2008 and 2016 (7% to 32%, respectively) (CHCF, 2017).

Table 4. Distribution of Formulary Structures among Health Insurance Products in California and Nationally, 2016

Tier Structures	Description of Prescription Drug Coverage by Tier	Cost-share Structure	California	United States
1 Tiered	Generic and some brand-name drugs; lowest cost drugs.	One cost-sharing amount regardless of drug type	5%	7%
2 Tiered	Plan preferred ^(a) , brand-name drugs and some generics; drugs are more expensive than Tier 1 drugs.	Typically have one payment for (1) generic ^(c) drugs and another, higher price for (2) brand-name drugs.	25%	5%
3 Tiered	Plan non-preferred ^(b) , brand-name drugs and some generics; drugs cost more than tier 2.	Typically have one payment for (1) generics, and two different payments for brand-name drugs, dividing them into (2) preferred, ^(d) with lower cost sharing, than the (3) non-preferred. ^(e)	45%	52%
4 Tiered	Specialty drugs such as life style drugs, (i.e., infertility, erectile dysfunction, weight loss, etc.), biologics or drugs requiring special handling or administration, and most drugs with costs greater than \$600 month.	Typically have the three tiers above, plus a fourth and highest payment level.	22%	32%
Other^a			2%	4%

Source: CHCF, 2017; CHCF, 2014.

Notes: Typical silver-level plan in Covered California cost sharing is as follows: \$15 generic drugs; \$55 preferred brand-name drugs; \$80 nonpreferred brand-name drugs; and 20% coinsurance for specialty drugs.

(a) "Plan preferred" included on formulary. (b) Non-preferred are not included on the formulary. (c) "Other" describes no formulary according to the CHCF survey. (d) A generic drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies. (e) A nonpreferred drug is one included on a formulary, but not on the preferred drug list; for example, a brand-name drug with a generic substitute.

Retail Price of Prescription Medications and Copayments/Coinsurance

Some Pharmacy Benefit Managers (PBMs) insert clauses into pharmacists' contracts that prohibit pharmacists from telling a customer whether there is a lower retail price for their prescription compared to the cost-sharing amount determined by a health insurance plan or policy. According to a survey conducted by the National Community Pharmacists Association in 2016, more than half (59%) of pharmacists encountered this restriction at least 10 times in a 30-day time period (NCPA, 2016). Additionally, when an enrollee pays a higher amount than the retail cost of a prescription at a pharmacy, PBMs may recoup the excess amount from the pharmacy, called a "clawback." Many pharmacists (83%) reported recently witnessing a clawback within the month preceding the survey; however, two-thirds of respondents said the practice is limited to certain PBMs (NCPA, 2016). Van Nuys and colleagues (2018) recently examined claims data to determine the frequency of overpayments, when an enrollee's copayment or coinsurance exceeds the retail cost of a prescription. The authors found overpayments affected 23% of all prescriptions and 28% of generic prescriptions. The mean overpayment was \$7.69; less than one-fifth (17%) of overpayments exceeded \$10.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 1021 newly mandates coverage for HIV/AIDS prevention therapies and proposes several amendments to existing law regarding cost sharing for outpatient prescription drugs. Therefore, this medical effectiveness review summarizes findings from evidence²⁸ on (1) the effectiveness of antiretroviral regimens for prevention of HIV/AIDS, and (2) the impact of cost sharing on outpatient prescription drug uptake and adherence. The literature searches for these subjects were performed separately and are presented as two distinct medical effectiveness reviews in this section.

For both evidence reviews, the conclusions below are based on the best available evidence from peer-reviewed and grey literature. 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. 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 figures in the “Study Findings” sections summarize CHBRP’s findings regarding the strength of the evidence for the effects of the HIV prevention therapies and cost-sharing provisions addressed by SB 1021. Separate figures are presented for treatment or service for which the bill would mandate coverage and for each outcome for which evidence of the effectiveness of a treatment is available. The title of the figure indicates the test, treatment or service for which evidence is summarized. For tests, treatments, and services for which CHBRP concludes that there is *clear and convincing*, *preponderance*, *limited*, or *inconclusive evidence*, the placement of the highlighted box indicates the strength of the evidence. If CHBRP concludes that evidence is insufficient, a figure that states “Insufficient Evidence” will be presented.

Medications to Prevent HIV/AIDS

Research Approach and Methods

SB 1021, as introduced, would require coverage for combination antiretroviral drug treatments that are medically necessary for the prevention of HIV/AIDS. This review summarizes findings from evidence from peer-reviewed literature on (1) the effectiveness of preventive therapies for HIV/AIDS, which include medications for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) and (2) the impact of health insurance coverage on adherence to prescribed HIV prevention therapies. Information regarding these treatments and their intended users is presented in Table 2 in the *Background* section.

Studies of the effectiveness and potential harms of medications for HIV prevention were identified through searches of PubMed, the Cochrane Library, AIDSInfo, and Web of Science. 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.

²⁸ Much of the discussion below is focused on reviews of available literature. However, as noted in the Medical Effectiveness approach document (available at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php; see p. 8), 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.

The search was limited to abstracts of studies published in English. The search for literature on PrEP was initially limited to studies published from 2010 to present as CHBRP had identified an existing systematic review published in 2012 by the Cochrane Review. However, during review, CHBRP identified a more recent systematic review published in 2016; therefore, literature returned from the initial search of PrEP-related search was reviewed from 2015 to the present. Similarly, CHBRP identified a 2014 review of PEP literature, which, in addition to several smaller supplementary reviews, forms the basis of the evidence review for PEP. Of the 1,200 articles found in the literature search, 83 were reviewed for potential inclusion in this report on SB 1021, and a total of 26 studies were included in the medical effectiveness review for HIV prevention therapies. The other articles were eliminated because they did not focus on therapies for HIV prevention, were of poor quality, or did not report findings from clinical research studies.

Key Questions

1. Are HIV prevention therapies (i.e., PrEP and PEP) effective in preventing HIV transmission?
2. What are the harms or adverse events associated with HIV prevention therapies?
3. Does having health insurance coverage for HIV prevention therapies (e.g., HIV PrEP and PEP) increase the likelihood that people at risk for HIV transmission will adhere to prescribed prevention therapies?

Methodological Considerations

Currently, the only FDA-approved therapy and dosing schedule for PrEP in the United States is a once-daily, single-pill combination of two HIV medications (tenofovir disoproxil fumarate [TDF] and emtricitabine [FTC]) known as Truvada®²⁹. Therefore, CHBRP chose to focus the medical effectiveness review on studies evaluating this regimen. More recent trials evaluating off-label use of pre-existing antiretroviral medications for PrEP regimens or new dosing methods of Truvada, such as injections or implantables, are excluded from CHBRP's primary evidence evaluation since they are not the standard of care recommended in guidelines and may be too new to be included in formularies. Comparatively, there are no drug regimens specifically approved by the FDA for PEP, due to ethical and practical considerations with attaining the data necessary to do so. CHBRP, therefore, uses the PEP regimen recommended in the 2016 United States Public Health Service guidelines for non-occupational exposures — the most recent PEP-related guidelines issued — as the treatment standard for this review (see the *Background* section for more information on guidelines for PrEP and PEP).

The literature base for PEP is divided into two primary domains based on risk pool: (1) use for occupational exposures (oPEP) in settings such as hospitals and dental practices and (2) use for non-occupational exposures (nPEP) that occur, for instance, during injection drug use or unprotected sexual encounters. However, because there is a common body of literature that informs PEP drug selection, the recommended regimen and dose for PEP is similar for all risk groups across all major PEP practice guidelines relevant to United States populations. Moreover, the evidence base for PEP treatments is comprised primarily of studies with lower-quality research designs (i.e., uncontrolled cohorts or case-control studies) or studies of PEP use in animal models; therefore, the certainty of the conclusions drawn from the evidence is limited. For these reasons CHBRP evaluated treatment effectiveness only for a general PEP population; however, the extent to which PEP may be differentially effective due to adherence issues between groups is noted when applicable.

²⁹ TDF-only regimens are permitted in instances when the patient presents with an allergy for FTC.

Outcomes Assessed

The effectiveness of antiretroviral therapies for HIV prevention is assessed using the following outcomes, which are often presented interchangeably:

1. HIV Incidence
2. HIV Risk Reduction
3. HIV Transmission

Adverse outcomes associated with HIV preventive therapies, as measured in the literature, included adverse health outcomes (i.e., decreased renal and hepatic function, and bone demineralization) and antiretroviral drug resistance.

The effectiveness of having health insurance coverage on HIV preventive therapy use behaviors was assessed using rate of prescriptions and rate of adherence to prescribed therapies for the prevention of HIV.

Study Findings

Effectiveness of medications that prevent HIV/AIDS

PrEP

As discussed in the methodologic considerations presented above, the only PrEP regimen and dosing schedule currently approved by the FDA and recommended by clinical practice guidelines is a daily, single-pill formulation of two medications currently used to treat HIV (tenofovir and emtricitabine) known as Truvada®; therefore, the effectiveness review presented below focuses on this regimen. Newer studies of PrEP evaluating off-label use of pre-existing antiretroviral medications for PrEP regimens or new dosing methods of Truvada were not included in the overall evaluation of effectiveness.

To date, thirteen major clinical trials have evaluated the effectiveness of daily, single-pill Truvada for HIV prevention across all high-risk groups in low to high income settings. While rates of relative HIV risk reduction with PrEP vary widely between trials (5% to 95%) and confidence intervals in the individual trials are large, a recent systematic review and meta-analysis by Fonner et al. (2016) including 19,491 participants from the 13 aforementioned trials demonstrated that PrEP significantly reduced the risk of HIV infection for all risk groups. Across the 11 included placebo-controlled trials, results of the meta-analysis showed that PrEP-users experienced a 51% reduction in risk (relative risk (RR)=0.49, 95% CI=0.33-0.73, p=0.001) and protective effects were even greater in the 3 trials with study arms assessing PrEP versus no-pill groups PrEP (RR=0.15, 95% CI=0.05-0.46; p=0.001). The review also included three observational studies (not included in the meta-analysis) among which the range of HIV incidence rates in the PrEP user groups (0.2-1.8 infections per 100 person-years) was comparatively lower than the incidence rates observed in the no-PrEP controls (0.7-5.3 infections per 100 person-years).

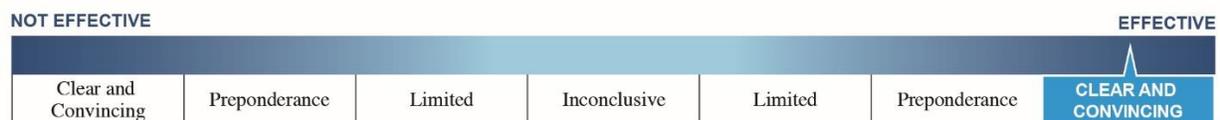
The degree to which PrEP reduces HIV infection risk is closely related to adherence. Among the seven RCTs that evaluated HIV incidence by adherence, results of the meta-analysis performed by Fonner and colleagues (2016) showed that higher levels of adherence were significantly associated with higher levels of risk reduction: in groups with high adherence (>70%), PrEP users experienced a 70% reduction in HIV infection risk as compared with placebo (RR=0.30, 95% CI=0.34-1.23, p<0.001). Among users with intermediate adherence (40%-70%) PrEP was associated a 45% HIV risk reduction (RR=0.55, 95%

CI=0.39-0.76, $p < 0.001$). PrEP did not provide a significant protective effect at low levels of adherence (<40%) compared with placebo (RR=0.95, 95% CI=0.74-1.23, $p=0.70$) (Fonner et al., 2016).

Meta-analysis of age-stratified data from three studies (Baeten et al., 2012; Grant et al., 2010; Van Damme et al., 2012) found that PrEP was not significantly effective for HIV prevention among users younger than 25 years (RR=0.71, 95% CI=0.47-1.06, $p=0.07$), however meta-regression did not identify age as a significant moderator of the relationship between PrEP and HIV infection risk (Fonner et al., 2016). Rather, study authors attributed the lack of observed effectiveness among young users to poor adherence.

Summary of findings regarding PrEP for HIV Prevention: There is clear and convincing evidence from 13 fair- and high-quality RCTs and 3 observational studies that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence.

Figure 3. Pre-Exposure Prophylaxis for HIV Prevention



PEP

PEP involves the provision of a 28-day course of three antiretroviral medications initiated within 72 hours of a known, or suspected, exposure to an active HIV infection. There are many antiretroviral medications that may be used for PEP, however the Centers for Disease Control and Prevention recommends a combination of three medications from two drug classes used to treat HIV — two nucleoside reverse transcriptase inhibitors [NRTIs] (Truvada, a coformulation of two NRTIs) and one integrase inhibitor (Raltegravir) — for all adults and adolescents. It should be noted that the preferred antiretroviral regimen specified in guidelines has not been approved by the FDA for PEP use and therefore represents off-label use of approved medication for HIV treatment.

Placebo-controlled RCTs evaluating specific PEP regimens in human contexts have not been conducted, owing to the generally accepted principle that it is unethical to randomize persons with confirmed HIV exposures to placebo or no treatment. Additionally, exposures to HIV are relatively rare and the risk of transmission from a single needle stick or intimate contact is low, ranging from 0.04% to 1.4% (Ford and Mayer, 2015; Patel et al., 2014); therefore, a clinical trial would have to enroll a very large number of subjects in order to have adequate power to assess effectiveness. Consequently, the evidence base for PEP treatment effectiveness is primarily comprised of observational studies, single-person case studies, or studies of PEP use in animal models, which do not meet CHBRP’s standard for high-quality research designs as described in Appendix C.

The evidence review performed for the World Health Organization’s combined 2013 PEP guidelines identified two systematic reviews suggesting that antiretroviral medications reduce the risk of HIV transmission when administered as PEP following exposures in occupational (Young et al., 2007) and non-occupational (Bryant et al., 2009) contexts. A Cochrane review of occupational PEP effectiveness studies included a single case-control study of 698 hospital workers in France, Italy, the United Kingdom, and the United States who were exposed to HIV through accidental needle sticks and offered prophylactic antiretroviral medication (Cardo et al., 1997). After controlling for HIV risk factors, it was determined that

workers who developed HIV following a workplace exposure (cases) and those who did not (controls) were equally likely to be offered PEP; however, cases were found to have had significantly lower odds of taking medications after exposure as compared with controls (odds ratio (OR)=0.19, 95% CI=0.06 to 0.52, $p<0.01$). Similarly, a systematic review of PEP effectiveness for non-occupational exposures included a single prospective observational study of low quality in which 200 HIV-negative Brazilian MSM received a supply of two antiretroviral medications and were instructed to initiate PEP after a high-risk sexual encounter (Schechter et al., 2004). At 24 months of follow-up, 10 out of the 11 confirmed HIV seroconversions occurred among men who reported high-risk sex and did not initiate PEP. The study authors did not conduct significance testing.

In addition to the two PEP effectiveness reviews included in the WHO guidelines, a 2016 update of the U.S. Public Health Service (USPHS) guidelines for non-occupational PEP found a large number of uncontrolled observational and case studies of patients who were offered PEP after suspected HIV exposures that suggest a potential benefit; however, the ability to draw conclusions about the effectiveness of PEP from these studies is limited because the majority of the studies had small sample sizes and research designs that do not meet CHBRP's standard of evidence (See Appendix C for more details).

As demonstrated in the previously-described PrEP effectiveness trials, high levels of adherence to the prescribed antiretroviral regimen is needed to obtain the greatest protective benefit; however, reported completion rates among PEP users is low (Ford et al., 2014). In a meta-analysis of 97 studies that included 21,426 PEP initiations for occupational and non-occupational exposures, Ford and colleagues (2014) observed an overall completion rate of 56.6% (95% CI=50.9-62.2%), which places most PEP users within the 'moderate' adherence category that was associated with only a 45% HIV transmission risk reduction among PrEP users (Fonner et al., 2016). With respect to exposure type, completion rates were highest for non-occupational exposures (65.6%, 95% CI=55.6-75.6%) and lowest among victims of sexual assault (40.2%, 95% CI=31.2-49.2%). When examined by age group, children were most likely to complete their PEP regimen (64.0%, 95% CI=41.2-86.8%) whereas adolescents exhibited the lowest completion rate 36.6%, 95% CI=4.0-69.2%). MSM had the highest reported PEP completion rates (67.2%, 95% CI=59.5-74.9%) out of any group analyzed in the review (Ford et al., 2014); however, this level of adherence was still lower than the optimal 70% threshold described by Fonner and colleagues (2016) in their recent analysis of PrEP effectiveness.

Several instances of potential PEP failures — defined as HIV seroconversion following timely initiation and perfect adherence — have been described in the medical literature. PEP failures are rare and difficult to confirm because assessment is generally based on patient self-report of adherence and high-risk behaviors during PEP use, but authors of a systematic review of 97 PEP studies with low- to moderate-quality study designs determined that PEP failures accounted for 3 out of the 37 seroconversions that occurred among the 8,007 participants who were considered eligible for PEP and completed treatment — a failure rate of 0.04 %. The remaining 34 seroconversions were retroactively attributed to poor adherence or repeated non-occupational exposures due to ongoing high-risk behaviors (Ford et al., 2014). In a more recent prospective study of 3,547 patients presenting for PEP following non-occupational exposures at a large community clinic in Canada from 2000 to 2014, researchers observed 10 seroconversions among the 2,731 patients who received PEP; only one case (0.04%) was determined to be a true PEP failure owing to repeat exposures among the other nine seroconverters (Thomas et al., 2015). All of the participants who seroconverted were MSM with a median age of 31 years who experienced a sexual exposure.

Summary of findings regarding PEP for HIV Prevention: There is limited evidence from a single historical case-control study among hospital workers, low-quality observational studies, and animal studies that PEP, as recommended by guidelines, is effective in preventing HIV transmission following occupational and non-occupational exposures. Adherence and follow-up in PEP studies is overall low and therefore limits CHBRP’s ability to draw conclusions about the relationship between adherence and effectiveness for PEP as well as the frequency of PEP failures.

Figure 4. Post-Exposure Prophylaxis for HIV Prevention



Harms of medications that prevent HIV/AIDS

PrEP

Adverse events: Among the eleven trials that evaluated the incidence of serious adverse events (AE), there was no difference in the risk of developing serious AEs between participants who received PrEP as compared with placebo (odds ratio=1.02, 95% CI=0.92-1.13, p=0.76); further, risk of a grade 3 or 4 AE was not moderated by adherence or biological sex. Two studies reported slight decreases in kidney function among PrEP recipients that resolved after discontinuation of PrEP (Martin et al., 2015; Solomon et al., 2016). Similarly, a few studies detected transient subclinical reductions in liver function (Choopanya et al., 2013; Van Damme et al., 2012) and bone mineral density among PrEP users (Kasonde et al., 2014; Liu et al., 2011).

Antiretroviral drug resistance: HIV resistance to first-line HIV medications for treatment, while not a direct harm, is an important consideration for high-risk PrEP users since the medications that comprise Truvada are also commonly used to treat active HIV infections. Resistance to Truvada, due to long-term low-dose exposure during PrEP, could limit a person’s treatment options should they develop a subsequent HIV infection. Six trials have assessed the incidence of drug resistance to antiretroviral medications among participants who underwent HIV seroconversion following PrEP use. Drug resistance overall was low, occurring among only 2% of the 533 participants who experienced HIV seroconversion across all study arms. However, a meta-analysis of drug resistance data from these trials found that the risk of developing resistance to either of the PrEP medications was significantly higher among PrEP users with an undetected pre-existing HIV infection at enrollment as compared with placebo (RR=3.34, 95% CI=1.11-10.06, p=0.03). PrEP use was not significantly associated with drug resistance detected among persons who experienced HIV seroconversion post randomization (Fonner et al., 2016).

Reproductive outcomes: In their recent systematic review of PrEP effectiveness, Fonner and colleagues (2016) identified two trials (FEM-PrEP and Partners PrEP) that assessed the effectiveness of hormonal contraception among women taking PrEP as compared with women randomized to placebo. Due to differences in study design, pooled analysis was not possible, but preliminary analyses of raw data suggested that pregnancies resulting from contraception failures may have been higher among PrEP users in both trials (FEM-PrEP: RR=1.48; Partners PrEP: RR=1.32). In study subanalyses, however, the observed differences in crude pregnancy rates were attenuated after adjustment for contraceptive type, study site, and age (Callahan et al., 2015; Murnane et al., 2014). Although not statistically significant, both

studies observed higher rates of contraceptive failure among PrEP users taking oral contraceptives as compared with injectables (Fonner et al., 2016).

A meta-analysis of adverse pregnancy outcomes, such as fetal loss and preterm birth, among women in FEM-PrEP and Partners PrEP showed that adverse pregnancy-related events did not differ between PrEP and placebo groups (RR=1.25, 95% CI=0.64-2.45, p=0.52). No differences in rates of adverse birth outcomes were observed when stratified by adherence or PrEP regimen (i.e., Truvada or tenofovir-alone) (Fonner et al., 2016).

Sexual risk compensation: In addition to biomedical safety analyses, many PrEP trials collected sexual behavior data, such as reported condom use and number of sexual partners, in order to assess PrEP users' willingness to engage in riskier sexual behaviors in response to a perceived reduction in risk of HIV transmission due to PrEP (known as "risk compensation"). According to a recent systematic review, condom use was evaluated as an outcome in eight clinical PrEP trials, which included MSM, women-only, and heterosexual partner study populations, and one comparative observational study of heterosexual partners. Due to differences in data collection strategies, meta-analysis was not possible, but the review authors noted that no significant differences in condom use were reported between PrEP and non-PrEP study arms in any of the studies; among all participants rates of unprotected sexual encounters remained stable or decreased from baseline to follow-up (Fonner et al., 2016).

Fonner et al. (2016) identified eight RCTs among MSM, women-only, and heterosexual partner study populations and three observational studies in MSM and heterosexual partners that conducted pre/post evaluations of the number of sexual partners with whom the participants engaged. As with condom use, meta-analysis was not possible, but there were no significant differences in the number of sexual partners that PrEP and non-PrEP users reported at follow-up across all study arms. Although the single trial that evaluated PrEP among injection drug users (Choopanya et al., 2013) collected patient-reported data regarding the number of sexual partners for both study arms, the results were reported for the entire cohort; therefore the differential impact of PrEP on risk compensation could not be assessed. However, study authors observed a significant 16 percentage point decrease (22% vs. 6%, p<0.001) in "sex with more than one partner" from baseline to the 72-month follow-up.

It should be noted that all participants in the PrEP trials included above received sexual risk reduction counseling and access to condoms throughout study enrollment, so the results described above may not be generalizable to PrEP users in routine care settings (Krakower et al., 2015).

PEP

The most common harm associated with PEP in the clinical literature is adverse events resulting from antiretroviral medication toxicities, which may account for up to 70% of PEP discontinuations and lapses in adherence (Thomas et al., 2015). As compared with other antiretroviral medications that have historically been used for PEP, the currently recommended regimen (i.e., Truvada plus Raltegravir) has the lowest observed discontinuation rate due to adverse events (1.9%, 95% CI=0.0-3.8%) (Ford et al., 2015). Therefore, the following discussion of adverse events is specific to this regimen since it is most likely to be used in clinical practice.

CHBRP identified two prospective observational safety studies that evaluated Truvada plus Raltegravir in the context of PEP. In the first study, 100 participants receiving PEP following high-risk sexual exposures at a large ambulatory care center in the United States used diaries to record any adverse medication-related events experienced during the 28-day treatment period; self-reported AE and pill count data were collected at 14-day and 28-day follow-up visits (Mayer et al., 2012). During the study period the most commonly reported side effects were nausea/vomiting (27%), diarrhea (21%), headache (15%), and

fatigue (14%). Most occurrences of AEs were mild to moderate and all reported AEs resolved after completion of PEP (Mayer et al., 2012). In a more recent study of Truvada plus Raltegravir use as PEP among 91 MSM recruited from two hospital centers in Australia, participants were evaluated once weekly for self-reported or clinical AEs and treatment adherence during the 28-day treatment period and then at weeks 5 and 12 for AE persistence (McAllister et al., 2014). After baseline, the most common self-reported AEs were mild to moderate fatigue (37%), diarrhea (25%), and nausea (24%). Although muscle pain accounted for only 9% of self-reported AEs, three participants had clinically detected creatinine phosphokinase elevations that presented as muscle pain indicative of rhabdomyolysis (a serious condition in which the muscles breakdown and release a protein that can harm the kidneys); however, these toxicities resolved following modifications to diet and exercise regimens. Elevated levels of alanine aminotransferase were detected in 19% of participants, but no cases of clinical hepatitis developed. No other serious AEs were detected and all events resolved upon completion of treatment (McAllister et al., 2014).

Although the findings related to adverse events during PEP use were consistent, both of the studies that met CHBRP's inclusion criteria had small sample sizes (i.e., 100 persons or less) that were comprised almost entirely of men, relied primarily on patient self-report, and were exclusively conducted in non-occupational settings; therefore, the generalizability of these findings to the overall PEP user population may be limited.

Coverage for medications that prevent HIV/AIDS

PrEP

CHBRP found no studies evaluating the impact of specific coverage for medications to prevent HIV on PrEP use. However, evidence from several observational studies suggests that access to healthcare through insurance coverage is, in general, positively associated with PrEP use (Marks et al., 2017; Patel et al., 2017). Among a cohort of 201 MSM recruited from three PrEP clinics in the United States, patients with insurance coverage were over three times more likely to be using PrEP three months after referral as compared with patients who were uninsured (OR=3.48, 95% CI=1.39-8.69). After adjusting for state Medicaid expansion practices and sociodemographic differences, insured patients were four times more likely to exhibit continued PrEP use (OR=4.49, 95% CI=1.68-12.01) (Patel et al., 2017). In addition, survey data from populations at high risk for HIV show that concerns regarding affordability of PrEP medications and PrEP-related medical visits are among the top reasons for discontinuing PrEP (Doblecki-Lewis et al., 2017; Holloway et al., 2017). In a follow-up survey of 173 former participants from two sites in a national PrEP demonstration study in which all patients were provided a 48-week course of daily PrEP, post-study PrEP continuation was significantly associated with having health insurance ($p < 0.001$). Moreover, 16% of respondents reported that wanting to continue PrEP motivated them to get health insurance coverage, and 8% selected a particular health plan based on the extent of PrEP coverage offered (Doblecki-Lewis et al., 2017).

Evidence from the literature also indicates that lapses in insurance coverage are important moderators of PrEP use. For example, between 2012 and 2015 Marcus et al. (2016) observed only two HIV seroconversions among a cohort of 972 PrEP users at Kaiser Permanente Northern California, both of which occurred during periods of insurance loss for two members. Follow-up studies from PrEP demonstration projects have also evaluated the impact of coverage loss on PrEP use. Among participants enrolled in an NIH-funded PrEP demonstration project in San Francisco, almost 12% attributed their discontinuation of PrEP to leaving their health plan (Liu et al., 2014). Similarly, 54% of survey respondents who reported discontinuing daily PrEP following participation in a national PrEP demonstration project cited cost or lack of health insurance as the reason for discontinuation (Doblecki-Lewis et al., 2017).

Summary of findings regarding coverage impacts on PrEP use: There is limited evidence that coverage for HIV prophylaxis is effective in encouraging PrEP use and adherence. Findings from five fair-quality observational studies indicate that having general health insurance coverage is effective in encouraging overall use and adherence to PrEP; however, CHBRP found no studies on insurance coverage specific to PrEP.

Figure 5. Impact of Insurance Coverage on PrEP Use



PEP

Information regarding coverage impacts on PEP use in the literature is limited: CHBRP identified a single 2009 study of PEP availability and barriers to use in Los Angeles (LA) County that addressed coverage as a moderator of PEP use. Study authors surveyed 117 LA County health care venues about their PEP-related services and found that only 14.5% of sites offered PEP, and that only 10 sites (8.5%) offered PEP to uninsured patients (Landovitz et al., 2009). In contrast, CHBRP did not identify any studies assessing patients deciding not to use PrEP on the basis of coverage deficits.

Summary of findings regarding coverage impacts on PEP use: There is insufficient evidence that health insurance coverage is effective in increasing use and adherence to PEP based on a single observational study.

Figure 6. Impact of Coverage on PEP Use



Summary of Findings

There is a preponderance of evidence that PrEP is effective in preventing HIV transmission and lowering the risk of HIV across all high-risk groups and among people with low to high income.

- The effectiveness of PrEP is moderated by adherence. PrEP users with moderate or high adherence in clinical trials have been shown to experience a protective benefit as compared with controls, whereas PrEP recipients with low adherence experience no significant protective benefit. Younger PrEP users (age 25 years or younger) are more likely to exhibit poor adherence compared with older users.
- PrEP use is not significantly associated with adverse health and reproductive health outcomes or with sexual risk compensation among users as compared with non-users.
- Resistance to Truvada, due to long-term low-dose exposure during PrEP, could limit a person's treatment options should they develop a subsequent HIV infection. Trial evidence indicates that drug resistance is significantly higher among persons who had an unknown active HIV infection

when they initiated PrEP, but medication resistance was not a significant factor among persons who acquire HIV after initiating daily PrEP.

Due to practical and ethical limitations, randomized controlled trials of PEP have not been conducted. There is, however, limited evidence from a single historical case-control study among hospital workers, low-quality observational studies, and animal studies that PEP is effective in preventing HIV transmission following occupational and non-occupational exposures.

- Adherence and follow-up in PEP studies is overall low and therefore limits CHBRPs ability to draw conclusions about the relationship between adherence and effectiveness for PEP as well as the frequency of PEP failures.
- PEP failures, while rare (observed failure rate=0.04%), have been described in the medical literature. Most PEP failures have been attributed to poor adherence, late initiation, and repeated exposures during treatment due to ongoing high-risk behaviors.
- Medication side effects have been implicated in up to 70% of PEP discontinuations. Common side effects associated with the PEP regimen recommended by the CDC are gastrointestinal distress, fatigue, and headaches. Serious adverse events are rare and resolve following completion or cessation of treatment.

CHBRP did not identify any studies assessing the impact of coverage for HIV prevention medications on the use of PEP or PrEP. However, there is a preponderance of evidence that having health insurance coverage is effective in encouraging overall use and adherence to PrEP, whereas there is insufficient evidence that coverage is effective in encouraging PEP use.

Cost-Sharing Provisions for Outpatient Prescription Drugs

Research Approach and Methods

Studies of the effects of cost sharing, including formulary tiering, on use of prescription drugs were identified through searches of the Cochrane Library, EconLit, Google Scholar, PubMed, and Web of Science. The search was limited to abstracts of peer-reviewed research studies that were published in English, conducted in the United States, and published from 2015 to present. For studies published prior to 2014, CHBRP relied on a literature search conducted in 2015 for its analysis of AB 339, which established the cost-sharing statutes that are amended by SB 1021. Since SB 1021 only amends selected elements of the law established by AB 339, CHBRP limited the evidence review to recent literature that broadly pertains to the impacts of cost sharing (i.e., copays/coinsurance, deductibles, and formulary tiering) on outpatient prescription drug use and adherence. Of the 83 articles found in the literature review, 11 were reviewed for potential inclusion in this report on SB 1021, and a total of 2 studies were included in the medical effectiveness review for cost sharing impacts on prescription drug use. The other articles were eliminated because they did not focus on the impacts of cost sharing on prescription drug use, were of poor quality, or did not report findings from clinical research studies.

The current review focused on studies conducted in the United States because findings from studies of cost sharing in countries with different types of health care systems may not be generalizable to the U.S. in general and to California in particular. The majority of CHBRP's analysis relies on three systematic reviews and additional smaller studies on cost sharing.

Key Question

1. What is the impact of cost sharing (i.e., copays/coinsurance, deductibles, formulary tiering) on outpatient prescription drug use and adherence?
2. What is the impact of prescription drug cost sharing on health outcomes?

Methodological Considerations

CHBRP found no studies that analyzed cost-sharing provisions as specific as those outlined in SB 1021. Instead, CHBRP presents reviews of literature whose findings are relevant to the broad cost-sharing provisions enumerated in SB 1021. For a general overview of the topic, we review studies of the effect of cost sharing on prescription drug use, including specialty drugs.

Outcomes Assessed

The effect of cost sharing and formulary modifications on prescription drug use was measured using the following outcomes:

1. Adherence to prescribed drug regimens
2. Utilization of prescribed drug regimens: defined as fills after prescription
3. Quality of life

Study Findings

It is well established in the literature that persons who face higher cost sharing use fewer services than persons with lower cost sharing (CHBRP, 2015). 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).

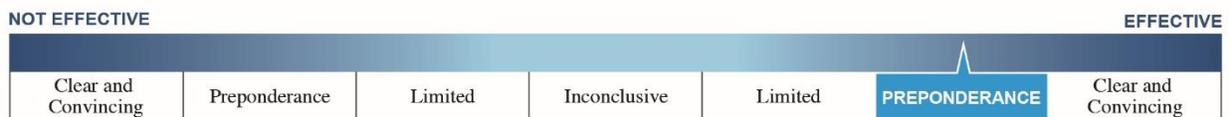
CHBRP identified four studies that examined the effects of cost sharing on use of specialty drugs. The first of these studies analyzed the association between highly-active antiretroviral therapy (HAART) prescription drug cost sharing and adherence to initial HAART in commercially insured patients with HIV. The authors found that increasing cost sharing (the combination of copayments, coinsurance, and deductibles) was associated with significantly lower odds of reaching the clinically meaningful adherence thresholds (Johnston et al., 2012). Another study looked at cancer treatment among adults with chronic myeloid leukemia who initiated imatinib, a tyrosine kinase inhibitor (TKI). TKIs are considered by some to be the most successful class of targeted therapies developed in cancer for improving survival (Experts in Chronic Myeloid Leukemia, 2013). The authors found that there was a 70% increase in the risk of discontinuing TKIs among patients with higher copayment requirements and patients with higher copayments were 42% more likely to be nonadherent. Another study consistent with these findings also showed that lower cost sharing contributes to a small improvement in quality of life (Ito et al., 2013). Other studies have shown mixed responses to changes in cost sharing. For multiple sclerosis drugs, anti-inflammatory drugs, and cancer drugs, when cost sharing was increased, patients did not show a statistically significant change in adherence compared to patients whose copayments stayed the same.

However, there was a small, but statistically significant, decrease in adherence for immunosuppressant agents (Goldman et al., 2007).

Summary of findings regarding cost sharing for prescription drugs:

There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.

Figure 7. Cost Sharing for Prescription Drugs



Summary of Findings

There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing reduce use of both essential and nonessential health care services.

- Persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
- The effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs; that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 1021 newly mandates coverage for medications to prevent HIV/AIDS and proposes several amendments to existing law regarding cost sharing for outpatient prescription drugs for DMHC-regulated plans and CDI-regulated policies.

In 2015, CHBRP analyzed AB 339, which established the law that SB 1021 intends to amend. The provisions established by AB 339 were effective as of January 1, 2017, and are due to sunset on January 1, 2020. The SB 1021 analysis will refer to relevant aspects of CHBRP's analysis for AB 339.

CHBRP initiated a quantitative assessment of the cost impacts of this provision regarding the coverage of drugs used in the prevention of HIV/AIDS using CHBRP's cost model and standard methodology (see the *Medications to Prevent HIV/AIDS* section below).

The provisions related to cost sharing and formulary tiers are discussed briefly after the *Medications to Prevent HIV/AIDS* section and again in more depth in the *Long-Term Impacts* section, where CHBRP also includes a projection to estimate the number of enrollees who might hit the cost-sharing limit in the future, assuming a constant upward trend in the cost of specialty drugs. CHBRP's analytic approach to SB 1021 and assumptions are available in Appendix D.

Medications to Prevent HIV/AIDS

CHBRP conducted a quantitative cost impact analysis for 2019 for this provision. The findings are presented in this Cost section and Table 10 in Appendix D.

Included here are the key assumptions used for the analysis of SB 1021's provision related to the coverage of medications to prevent HIV/AIDS. Full methodology and detailed assumptions for the analysis are in Appendix D.

Key assumptions:

- CHBRP assumes Truvada®, which is used for prevention of HIV/AIDS in pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), will continue to remain as the only single tablet preventive HIV/AIDS medication on the market in 2019 for the analysis of cost impact.
- Since the potential impact change of this provision affects those enrollees who use HIV drugs for prevention purposes, the analysis assumes enrollees that had not been diagnosed with HIV as of the date of the first HIV prevention drug usage in 2016 are those who do not have HIV and are likely using HIV/AIDS drugs for preventive purposes.

Baseline and Postmandate Benefit Coverage

Current benefit coverage of the provisions in SB 1021 was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this CHBRP survey represent 72% of enrollees with private market health insurance that can be subject to state mandates. Below is a summary of the findings related to baseline benefit coverage and projected postmandate benefit coverage.

Currently, there are 23,433,000 enrollees with health insurance subject to state-level benefit mandates and 15,923,000 of these enrollees (or 68%) have health insurance subject to SB 1021's provision on medications to prevent HIV/AIDS. CHBRP found of these enrollees (100%) have health insurance that is fully compliant with the HIV/AIDS medications for prevention provision of SB 1021. Please see Table 10 in Appendix D.

Postmandate, 100% of enrollees would continue to have health insurance that is fully compliant with the HIV/AIDS medications for prevention provision of SB 1021. Thus, there is no change in the benefit coverage of HIV/AIDS medications for prevention post-mandate.

Baseline and Postmandate Utilization

MarketScan commercial claims and enrollment data for California in 2016 were used to quantify the number of enrollees using HIV/AIDS drugs for prevention, both for pre- and post-exposure prophylaxis (PrEP and PEP, respectively). At baseline, it is estimated there are 23,267 commercial market users of PrEP and 6,708 users of PEP. Based on the bill language, Please refer to Appendix D for details on the methodology used to obtain utilization estimates.

Baseline and Postmandate Per-Unit Cost

Baseline costs per enrollee (\$2,220 for PrEP and \$2,000 for PEP) were estimated using MarketScan commercial claims and enrollment data for California in 2016 (Table 10 in Appendix D).

Baseline and Postmandate Expenditures

SB 1021's mandate on coverage of medications for HIV/AIDS prevention does not change total net annual expenditures because there would be no change in benefit coverage of HIV/AIDS medications for prevention.

Premiums

No change in premiums is expected as a result of SB 1021's mandate on coverage of medications for HIV/AIDS prevention.

Enrollee expenses

No change in related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits is expected as a result of SB 1021's mandate on coverage of medications for HIV/AIDS prevention.

The average monthly enrollee expenditures for drugs used to prevent HIV infection range between \$48 and \$156 for DMHC-regulated plans and \$113 and \$134 for CDI-regulated plans. These expenditures include co-payments and deductibles. CHBRP found about 74% of enrollees had copayments for Truvada that were less than or equal to \$50 per prescription; about 94% had co-insurance of less than \$100 per prescription. And, approximately 10% of claims include those where there is \$0 (no) copayment or co-insurance for 30-day Truvada prescription. These findings are consistent with a report on Covered California plans that found Truvada was listed as a Tier 2 or preferred drug on all of its plans (King et al., 2016).

CHBRP does not have access to any data to quantify the impact of financial support and patient assistance programs and how they impact enrollee expenses. Patient assistance programs offer

copayment relief for private insurance enrollees if they meet certain financial requirements (Smith et al., 2017). Gilead Sciences Inc., manufacturer of Truvada, also offers a patient assistance program that assists with patient co-payment expenses (Truvada for PrEP Medication Assistance Program³⁰).

Out-of-pocket spending for covered and noncovered expenses

CHBRP assumes insured individuals who have coverage for Truvada would not acquire Truvada without insurance and pay the full price of the drug completely out-of-pocket (i.e., without insurance). For insured enrollees where Truvada is covered and enrollees pay a copay or coinsurance amount, enrollees may be able to offset some of their financial burden of out-of-pocket expenses for Truvada via patient assistance programs if enrollees meet financial qualifications for assistance.

Potential cost offsets or savings in the first 12 months after enactment

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions related to coverage of medications for HIV/AIDS prevention in SB 1021.

CHBRP estimates no increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies given no increase in premiums.

Cost Sharing for Outpatient Prescription Drugs

Enrollee Out-of-Pocket Cost-Sharing Limitations

CHBRP assumes plans and policies are in compliance with the cost-sharing limits as introduced by AB 339. While SB 1021 does not change the cost-sharing limits currently in law, given the increasing trend in drug prices, CHBRP assumes more enrollees will hit the cost-sharing limits over time assuming no other changes to the market.

Currently, there are 23,433,000 enrollees with health insurance subject to state-level benefit mandates and 15,923,000 of these enrollees — or 68% — have health insurance subject to SB 1021's provision on cost-sharing limits. AB 339 introduced cost-sharing limits for prescription drugs for all of these enrollees, thus at baseline, assuming full compliance with the law, CHBRP estimates 100% of enrollees have health insurance that is fully compliant with the cost-sharing limit. Postmandate, 100% of enrollees would continue to have health insurance that is fully compliant with the cost-sharing limits of SB 1021. Thus, there is no change in the benefit coverage for this provision.

In its analysis of AB 339 in 2015, CHBRP estimated 17.1 million enrollees were subject to AB 339; however, only about 0.8% of enrollees (130,502 enrollees) in these plans and policies subject to AB 339 had outpatient prescription drug claims that would exceed the limitation (note, in the CHBRP analysis of AB 339, the cost-sharing limit examined was 1/24 of annual out-of-pocket maximum, which translated to about \$260 per month). CHBRP estimated a utilization increase of an additional 3,174 enrollees who previously did not use prescription drugs (increase of 2.43%) but who would with the passage of AB 339. The level of utilization change postmandate estimated by CHBRP was rather low due a variety of factors including (1) low prevalence of conditions that required costly specialty prescription drugs, (2) the relatively small number of enrollees with high cost-sharing requirements for prescription drugs, and (3) the low number of group plans and policies without a maximum dollar amount limit on cost sharing for

³⁰ [Truvada® for PrEP Medication Assistance Program](#)

prescription drugs given that in 2015 Covered California instituted cost-sharing limits in their plans and products, and plans outside of Covered California may have begun to include limits in response.

A projection of the number of enrollees hitting the cost-sharing limits in 2019 and beyond to 2021 is provided and discussed in the *Long-Term Impacts* section.

Outpatient Prescription Drug Formulary Tiers

CHBRP is unable to estimate the cost for those enrollees in plans that would necessitate a change in formulary due the mandate because of CHBRP's inability to predict decisions made by carriers in coordination with pharmacy benefit managers (PBMs) in restructuring formularies. SB 1021 also *allows* plans and policies to place biologic therapeutic equivalents on tiers lower than level 4.

CHBRP includes a discussion on this issue in the *Long-Term Impacts* section with special attention to the changing market and emerging shifts in the relationship between insurance carriers and PBMs that might affect placement of drugs on formularies in the future.

Currently, there are 23,433,000 enrollees with health insurance subject to state-level benefit mandates and 5.45 million of these enrollees — or 23% — have health insurance subject to SB 1021's provision on formulary tiering. Based on the CHBRP carrier survey, it is estimated that all of these enrollees (100%) have health insurance that is fully compliant with the prohibition of more than four tiers on a plan's drug formulary. Postmandate, 100% of enrollees would continue to have health insurance that is fully compliant with the 4 tiered formulary structure provision of SB 1021. Thus, there is no change in the benefit coverage for this provision.

Retail Price of Prescriptions

As described in the *Policy Context* section, this provision codifies existing DMHC regulation for all DMHC- and CDI- regulated plans and policies (except Medi-Cal). It would impact 15,923,000 enrollees — or 68% — of the 23,433,000 enrollees with DMHC- and CDI- regulated plans and policies subject to state-level benefit mandates. CHBRP assumes insurance carriers would need to work closely with pharmacies and pharmacy benefit managers to ensure compliance with this existing DMHC regulation that would also apply to CDI-regulated policies. However, CHBRP does not have access to data that describes the percent of prescription copayments/coinsurance that are above the retail cost. Thus, CHBRP does not address this provision of SB 1021 within this cost section.

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.

Potential cost of exceeding Essential Health Benefits

As explained in the *Policy Context* section, SB 1021's provisions do not to exceed the definition of EHBs in California.

Postmandate changes in the number of uninsured persons³¹

No change in the number of uninsured persons is expected due to the enactment of SB 1021.

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 1021.

How lack of benefit coverage results in cost shifts to other payers

Given 100% coverage of medications used for the prevention of HIV/AIDS, CHBRP assumes there would not be a shift in cost to other payers due to a lack of coverage of drugs for prevention of HIV/AIDS or any of the other provisions in SB 1021.

³¹ See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

PUBLIC HEALTH IMPACTS

Estimated Public Health Outcomes

CHBRP projects no public health impact related to the provisions of SB 1021.

CHBRP concludes that passage of SB 1021 would have no short-term³² public health impact because carriers report that 100% of enrollees currently have coverage for these benefits or these provisions are required by current law; thus, no change in coverage or utilization would occur within the first 12 months of implementation. Furthermore, the current law that limits coinsurance/copayments for prescription drugs does not sunset until January 1, 2020, which is outside of CHBRP's short-term (12-month) analytic timeframe. For these reasons, CHBRP also concludes that SB 1021 would have no impact on premature death; societal economic losses; or existing disparities in health outcomes by gender, race/ethnicity, sexual orientation/gender identity or other social determinants.

See the *Long-Term Impacts* section for more in-depth discussion about the effects of increased cost sharing were the current law to sunset in 2020.

³² CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact³³ of SB 1021, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. This section is largely qualitative and based on the existing evidence available in the literature; however, CHBRP additionally provides estimates on the costliest drugs in the market in 2016 and estimates the number of enrollees hitting the cost-sharing limits specified in SB 1021 projected into 2021, assuming the historic upward trend in cost of specialty drugs continues.

Medications to Prevent HIV/AIDS

Utilization and Cost

Recent studies have reported that there is an upward trend in utilization of drugs for the prevention of HIV/AIDS (Nikolopoulos et al., 2017; Tuller, 2018). It is reasonable to assume that this increase in utilization will continue beyond the first 12 months of implementation, should SB 1021 pass, as awareness continues to increase among providers and consumers.

Truvada® is currently the only single-tablet drug on the market for PrEP. However, in 2017 the FDA approved a generic formulation of Truvada, and there are new compounds and formulations for PrEP in the pipeline. It is unclear when exactly these products will come to market and how it will affect the utilization and cost of Truvada for use of prevention of HIV/AIDS. It is reasonable to assume that if the appearance of a generic formulation is widely used and offered at a lower price, utilization and cost of Truvada would decrease.

AB 339 mandated the coverage of single-tablet antiretroviral therapy (ART) drugs that are as effective as multitablet regimens for treatment of HIV/AIDS. In its analysis of AB 339, CHBRP reviewed the 2016 published formularies for Covered California plans. CHBRP found there were only a few plans where the HIV/AIDS treatment drugs were placed on tier 4 of the formulary; these plans enrolled less than 0.05% of the states' insured population. Plans that covered any single tablet HIV/AIDS drugs tended to place them on tier 2 of the formulary with a maximum copayment of \$50 per prescription. At this level of copayment, enrollees would not exceed the monthly copayment limits as mandated in AB 339 (and SB 1021), which are discussed in the sections below. SB 1021 removes the sunset provision of AB 339. Therefore CHBRP assumes plans will continue to comply with the AB 339 provisions. In the absence of SB 1021, the sunset of AB 339 would occur, but it is not clear how plans will react. Such as whether enrollees would lose coverage for HIV/AIDS drugs or if drugs would be placed on higher cost tiers, especially given there were already shifts towards coverage and lower tier placement of HIV/AIDS drugs prior to the enactment of AB 339. Plans and policies might change in the future due to other unforeseen reasons.

Public Health

Estimating the cost-effectiveness of PrEP is important to the public health field to help ascertain the most impactful spending of prevention dollars. Krakower et al. (2015) reported ambiguous results from their review of cost-effectiveness literature regarding PrEP therapy. In general, the study models showed PrEP was cost-effective when administered to high-risk populations that were highly adherent to the regimen. They cited a range of quality-adjusted-life-year (QALY) estimates for U.S. programs ranging from \$32,000 to \$300,000 per QALY. Standard willingness-to-pay thresholds are generally about \$50,000/QALY. A

³³ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

more recent cost-effectiveness model compared HIV prevention strategies of “test-and-treat” and PrEP among MSM in Los Angeles. The model showed that PrEP cost \$27,863/QALY as compared with the test-and-treat cost of \$19,302/QALY (as compared with the status quo of testing and initiating treatment at CD4 cell count below 500). The authors conclude that in areas with a higher prevalence of HIV/AIDS, PrEP, with recommended adherence, is considered a cost-effective HIV prevention method along with test-and-treat (Drabo et al., 2016).

Cost Sharing for Outpatient Prescription Drugs

Utilization and Cost

As discussed in the *Policy Context* section, one of the main provisions of AB 339 was to require DMHC- and CDI-regulated nongrandfathered health plans or policies offered, amended, or renewed on or after January 1, 2017, to limit the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for up to a 30-day supply to not more than \$250 (\$500 for products with actuarial value at, or equivalent to, the bronze level). This provision in AB 339 was in alignment with that of Covered California, which adopted regulations in 2015 (and went into effect in 2016) that required qualifying health plans sold through Covered California to limit enrollee cost sharing for a prescription drug to \$250/month for a 30-day supply of drugs in tier 4 (\$500 for enrollees in a bronze plan). In CHBRP’s assessment of the potential impacts of AB 339, it found most of the health plans subject to the cost-sharing limits already had a maximum dollar amount limit on cost sharing — likely due to changes in the Covered California regulation stimulating changes in all other markets — thus, the estimated impact of AB 339 on expenditures and premiums was low.

SB 1021 and outpatient drug cost-sharing limits

If drug prices continue to rise, it is expected there will be more enrollees who hit the cost-sharing limits in future years. Using MarketScan data, CHBRP summarizes the most expensive drugs in the market in 2016 in Table 5, defined as those drugs that would cost enough that an enrollee could potentially hit the \$250 per prescription for up to a 30-day supply out-of-pocket cost-sharing limit. For this, CHBRP identified all drugs which would hit this limit by identifying those with a cost per prescription of at least \$625 for a 30-day prescription; this value was determined by using a bronze actuarial value with member average cost of 40% of allowed cost ($625 \times 0.4 = \$250$ out of pocket).

Table 5. Top 25 Drugs with Highest Total Spending in 2016 among Enrollees Subject to SB 1021 in 2016

Product Name (condition)	Total 2016 Spend on Drugs among Enrollees Subject to SB 1021 (in MarketScan sample)	Cost per Prescription (Based on Total 2016 Spend)
HUMIRA® (inflammatory arthritis)	\$603,000,000	\$4,463
ENBREL® (inflammatory arthritis)	\$340,000,000	\$3,910
TRUVADA® (HIV/AIDS)	\$270,000,000	\$1,489
HARVONI® (hepatitis C)	\$198,000,000	\$23,699
COPAXONE® (multiple sclerosis)	\$134,000,000	\$5,390
TECFIDERA® (multiple sclerosis)	\$111,000,000	\$6,024
REVLIMID® (multiple myeloma)	\$94,000,000	\$11,594
ATRIPLA® (HIV/AIDS)	\$88,000,000	\$2,337
STELARA® (Crohn's disease)	\$79,000,000	\$6,331
TRIUMEQ® (HIV/AIDS)	\$77,000,000	\$2,373
IBRANCE® (breast cancer)	\$72,000,000	\$10,659
GILENYA® (multiple sclerosis)	\$70,000,000	\$6,277
GENVOYA® (HIV/AIDS)	\$66,000,000	\$2,585
STRIBILD® (HIV/AIDS)	\$62,000,000	\$2,732
SOVALDI® (hepatitis C)	\$62,000,000	\$26,620
XYREM® (narcolepsy)	\$59,000,000	\$9,880
VIREAD® (hepatitis B or HIV/AIDS)	\$55,000,000	\$970
COMPLERA® (HIV/AIDS)	\$53,000,000	\$2,436
SPRYCEL® (leukemia)	\$52,000,000	\$9,860
OTEZLA® (psoriasis)	\$51,000,000	\$2,574
GLEEVEC® (leukemia)	\$51,000,000	\$9,191
LATUDA® (depression)	\$48,000,000	\$986
EPCLUSA® (hepatitis C)	\$47,000,000	\$24,657
LIALDA® (ulcerative colitis)	\$44,000,000	\$687
COSENTYX® (psoriasis)	\$44,000,000	\$5,575

Source: California Health Benefits Review Program, 2018.

Note: This is the list of top 25 ranked specialty drugs in 2016 MarketScan data among prescription with at least \$625 30-day normalized allowed costs per prescription. The MarketScan sample is only about 1/8 of the total insured population, so the total spending reported here is lower than the total spend for the total insured population.

These top 25 drugs shown in Table 5 represent 0.8% of the total prescriptions in California; however, they represent about 25% of the total cost of drugs in the state (see Table 6). Specialty drugs in general (as defined as prescriptions having a cost of least \$625 per 30 days) represent 2% of the total number of prescriptions, but account for about 54% of total costs for drugs. This underscores the notion that while high-cost drugs represent a somewhat small proportion of overall drugs used by consumers, they account for a fairly high proportion of costs.

Table 6. Costs and Use of the Top 25 Drugs and Specialty Drugs in Relation to all Outpatient Drugs

Category	% of Allowed Cost	% of Total Prescriptions(a)
Top 25 Drugs (in Table 5)	25.6%	0.8%
All Specialty Drugs	54.5%	2.2%
All Outpatient drugs	100.0%	100.0%

Source: California Health Benefits Review Program, 2018.

Note: Specialty drugs in 2016 MarketScan data, defined as prescriptions with at least \$625 30-day normalized allowed costs per prescription. Based on California population of approximately 1.8 million. (a) Adjusted for 30-day prescription

CHBRP projections on rising drug costs and enrollees hitting cost-sharing limits in future, 2021 projection

To assess the potential impact of rising drug prices on the number of enrollees who hit the cost-sharing limits outlined in SB 1021, CHBRP provides a long-term projection of how many enrollees may hit the cost-sharing limit in future years, based on specialty drug price growth (assumed to be 11% annual unit cost growth based on published trends from the 2016 Drug Trends Report from Express Scripts®).

To complete this projection analysis, CHBRP used the 2016 MarketScan commercial claims data to compile a list of outpatient prescription drugs based on their cost that are likely to be subject to the cost sharing limit (see Appendix D for details on methods and assumptions). The out-of-pocket cost-sharing limits are fixed; therefore, as drug costs increase, more drugs and enrollees get closer to the out-of-pocket cost-sharing limit. Because of the uncertainty around the approval of new drugs that come to market, changes in costs due to competition, and the inability to predict new users, CHBRP limits the analysis to drugs in the 2016 market and how the trend of rising drug costs applied to these drugs will impact the number of enrollees hitting the cost-sharing limits laid out in SB 1021 in 2021. CHBRP also assumes no change to the copayment over time; thus, a drug with a \$10 copay in 2016 is assumed to still have a \$10 copay on that drug in 2021. CHBRP assumes all enrollees are in a bronze equivalent plan in this analysis, such that the projection estimates provided are the **maximum** number of enrollees who may hit the cost-sharing limit (i.e., upper limit). The likely number of enrollees hitting the limit would be lower given not all enrollees would be in a bronze equivalent plan.

CHBRP completed a 3-year projection of the number of enrollees hitting the cost-sharing limit of \$250 per prescription for up to a 30-day supply. Table 7 summarizes the findings of the projection analysis. In 2019, it is estimated there will be a maximum of 834,500 enrollees hitting the cost-sharing limit of \$250 per prescription for up to a 30-day supply, these enrollees represent 5.24% of all enrollees in California subject to SB 1021. The number of enrollees potentially hitting the cost-sharing limit grows each year as drug prices trend upwards by the 11% annual increase in costs that was applied in this analysis. By 2021,

the number of enrollees hitting the cost-sharing limit is estimated to be a maximum of about 1,097,100 enrollees, or 6.8%.

Table 7. Maximum Projected Number of Enrollees Who Hit the Cost-Sharing Limit of \$250 Per Month for 30-Day Supply of Outpatient Prescription Drugs As Mandated in AB 339, Which Would Be Extended Without a Sunset by SB 1021, Estimated for the California Mandate Population

Year	Maximum Projected Number of Enrollees who Hit Cost-sharing Limit, Estimated for the California Mandate Population ^(a)	Maximum Projected % of Enrollees who Could Potentially Hit the Cost-sharing Limit
2019	834,500	5.24%
2020	967,700	6.08%
2021	1,097,100	6.89%

Source: California Health Benefits Review Program, 2018.

Note: (a) rounded to the nearest 100; California mandate population is 15,923,000 enrollees. Based on MarketScan claims database sample data. Because CHBRP assumes all enrollees in a bronze equivalent plan in this analysis, the projection estimates provided here are the **maximum** number of enrollees who may hit the cost-sharing limit/cap (i.e., upper limit). The likely number of enrollees hitting the limit would be lower given not all enrollees would be in a bronze equivalent plan.

Interaction between rising drug costs and policies on cost-sharing limits

There are current policy debates on how best to protect consumers from rising drug costs – policy solutions include:

- Outpatient drug cost-sharing limits (such as those examined here) to relieve patient out-of-pocket expenses (Robinson et al., 2016).
- Limits and transparency around drug pricing practices of drug manufacturers (Sarpatwari et al., 2016).
- Regulation around how pharmacy benefit managers (PBMs) that contract with health plans to administer coverage of drugs negotiate drug placement on formularies; current pricing practices may limit cheaper versions of drugs, for example biosimilar drugs that are cheaper versions of expensive biologic drugs (Riley, February 16, 2018).
- Restrictions on how PBMs obtain and distribute rebates or discounts to plans and to consumers (Egilman et al., 2018; Falit et al., 2015).
- Use of value-based insurance design, including value-based formularies, such that cost-sharing corresponds/aligns with the cost-effectiveness of the intervention or medication covered by insurance, (Chernew, 2016;Chernew, 2010;Yeung, 2017).

Because of this heightened interest at the state and federal level in finding policy solutions to shield consumers from rising drug costs, it is possible there will be major policy shifts in the near future that change the current system of pricing and cost sharing. The market is also shifting rapidly; in March 2018, UnitedHealthcare, one of the largest insurers in the U.S., announced that it would pass along all of the money it receives from drug rebates from pharmaceutical and biotechnology manufacturers to their

enrollees in fully insured products starting in 2019. This might disrupt the current complex model of interaction between drug manufacturers, PBMs, and health insurers and how drug pricing is impacted by the relationship.

Outpatient Prescription Drug Formulary Tiers

Limits to formulary tiers as another means of controlling cost sharing

Consumer cost-sharing burden stemming from outpatient drug costs may also be limited with the use of regulations that limit the number of formulary tiers and the placement of drugs into the highest cost tier. The highest cost formulary tiers, which are typically reserved for specialty drugs, require a co-insurance percentage (e.g., consumer pays 20% of the price of a prescription drug) rather than a standard dollar copayment amount (e.g., a fixed \$25 per prescription). AB 339 addressed formularies by including the definitions of formulary tier groupings in the legislation. SB 1021 proposes a firm limit of four formulary tiers, which is consistent with Covered California and Medi-Cal formulary standards.

CHBRP found 100% of carriers surveyed for the analysis had the four-tier formulary structure in place. While the number of tiers will not change over time due to the mandates SB 1021 would retain, the decisions regarding the placement of drugs in these four tiers may change over time as the health care market — namely the relationships between carriers and PBMs — is rapidly changing. It is notable that in March 2018 there was another merger announcement between a carrier and PBM (Cigna and Express Scripts), adding to the list of mergers that have already occurred. Aetna and CVS Health, which operates Caremark PBM, announced a merger of services in December of 2017. In 2015, UnitedHealth Group expanded its pharmacy business, OptumRx, when it acquired Catamaran, a PBM. These mergers reflect a changing market and may change current practices that determine where drugs are placed on formularies.

APPENDIX A TEXT OF BILL ANALYZED

On February 8, 2018, the California Senate Committee on Health requested that CHBRP analyze SB 1021.

SENATE BILL

No. 1021

**Introduced by Senator Wiener
(Principal coauthor: Senator
Atkins)**

February 7, 2018

An act to amend and repeal Section 1342.71 of the Health and Safety Code, and to amend and repeal Section 10123.193 of the Insurance Code, relating to health care coverage.

legislative counsel's digest

SB 1021, as introduced, Wiener. Prescription drugs.

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 also provides for the regulation of health insurers by the Department of Insurance.

Existing law prohibits the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment of individuals with health conditions and from reducing the generosity of the benefit for enrollees or insureds with a particular condition. Existing law, until January 1, 2020, provides that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as specified. Existing law, until January 1, 2020, requires a nongrandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary.

This bill would extend those provisions indefinitely. The bill would prohibit a drug formulary maintained by a health care service plan or health insurer from containing more than 4 tiers, and would permit a biologic with a therapeutic equivalent to be placed on a tier other than

tier 4, as specified. The bill would require a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy's retail price is less than the applicable copayment or coinsurance amount.

Existing law requires a plan contract or policy to cover a single-tablet prescription drug regimen for combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, as specified. This bill would extend that coverage requirement to combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, as specified. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1342.71 of the Health and Safety Code,
- 2 as amended by Section 175 of Chapter 86 of the Statutes of 2016,
- 3 is amended to read:
- 4 1342.71. (a) The Legislature hereby finds and declares all of
- 5 the following:
- 6 (1) The federal Patient Protection and Affordable Care Act, its
- 7 implementing regulations and guidance, and related state law
- 8 prohibit discrimination based on a person's expected length of life,
- 9 present or predicted disability, degree of medical dependency,
- 10 quality of life, or other health conditions, including benefit designs
- 11 that have the effect of discouraging the enrollment of individuals
- 12 with significant health needs.
- 13 (2) The Legislature intends to build on existing state and federal
- 14 law to ensure that health coverage benefit designs do not have an
- 15 unreasonable discriminatory impact on chronically ill individuals,
- 16 and to ensure affordability of outpatient prescription drugs.
- 17 (3) Assignment of all or most prescription medications that treat
- 18 a specific medical condition to the highest cost tiers of a formulary

1 may effectively discourage enrollment by chronically ill
2 individuals, and may result in lower adherence to a prescription
3 drug treatment regimen.

4 (b) A nongrandfathered health care service plan contract that is
5 offered, amended, or renewed on or after January 1, 2017, shall
6 comply with this section. The cost-sharing limits established by
7 this section apply only to outpatient prescription drugs covered by
8 the contract that constitute essential health benefits, as
defined in 9Section 1367.005.

10 (c) A health care service plan contract that provides coverage
11 for outpatient prescription drugs shall cover medically necessary
12 prescription drugs, including nonformulary drugs determined to
13 be medically necessary consistent with this chapter.

14 (d) (1) Consistent with federal law and guidance, the formulary
15 or formularies for outpatient prescription drugs maintained by the
16 health care service plan shall not discourage the enrollment of
17 individuals with health conditions and shall not reduce the
18 generosity of the benefit for enrollees with a particular condition
19 in a manner that is not based on a clinical indication or reasonable
20 medical management practices. Section 1342.7 and any regulations
21 adopted pursuant to that section shall be interpreted in a manner
22 that is consistent with this section.

23 (2) For combination antiretroviral drug treatments that are
24 medically necessary for the treatment *or prevention* of AIDS/HIV,
25 a health care service plan contract shall cover a single-tablet drug
26 regimen that is as effective as a multitablet regimen unless,
27 consistent with clinical guidelines and peer-reviewed scientific
28 and medical literature, the multitablet regimen is clinically equally
29 or more effective and more likely to result in adherence to a drug
30 regimen.

31 (e) (1) With respect to an individual or group health care service
32 plan contract subject to Section 1367.006, the copayment,
33 coinsurance, or any other form of cost sharing for a covered
34 outpatient prescription drug for an individual prescription for a
35 supply of up to 30 days shall not exceed two hundred fifty dollars
36 (\$250), except as provided in paragraphs (2) and (3).

37 (2) With respect to products with actuarial value at, or equivalent
38 to, the bronze level, cost sharing for a covered outpatient
39 prescription drug for an individual prescription for a supply of up

1 to 30 days shall not exceed five hundred dollars (\$500), except as
2 provided in paragraph (3).

3 (3) For a health care service plan contract that is a “high
4 deductible health plan” under the definition set forth in Section
5 223(c)(2) of Title 26 of the United States Code, paragraphs (1)
6 and (2) of this subdivision shall apply only once an enrollee’s
7 deductible has been satisfied for the year.

8 (4) For a nongrandfathered individual or small group health
9 care service plan contract, the annual deductible for outpatient
10 drugs, if any, shall not exceed twice the amount specified in
11 paragraph (1) or (2), respectively.

12 (5) For purposes of paragraphs (1) and (2), “any other form of
13 cost sharing” shall not include a deductible.

14 (f) (1) If a health care service plan contract for a
15 nongrandfathered individual or small group product maintains a
16 drug formulary grouped into tiers that includes a fourth tier, a
17 health care service plan contract shall use the following definitions
18 for each tier of the drug formulary:

19 (A) Tier one shall consist of most generic drugs and low-cost
20 preferred brand name drugs.

21 (B) Tier two shall consist of nonpreferred generic drugs,
22 preferred brand name drugs, and any other drugs recommended
23 by the health care service plan’s pharmacy and therapeutics
24 committee based on safety, efficacy, and cost.

25 (C) Tier three shall consist of nonpreferred brand name drugs
26 or drugs that are recommended by the health care service plan’s
27 pharmacy and therapeutics committee based on safety, efficacy,
28 and cost, or that generally have a preferred and often less costly
29 therapeutic alternative at a lower tier.

30 (D) Tier four shall consist of drugs that are biologics, drugs that
31 the FDA or the manufacturer requires to be distributed through a
32 specialty pharmacy, drugs that require the enrollee to have special
33 training or clinical monitoring for self-administration, or drugs
34 that cost the health plan more than six hundred dollars (\$600) net
35 of rebates for a one-month supply.

36 (2) In placing specific drugs on specific tiers, or choosing to
37 place a drug on the formulary, the health care service plan shall
38 take into account the other provisions of this section and this
39 chapter.

1 (3) A health care service plan contract may maintain a drug
2 formulary with fewer than four tiers. *A health care service plan*
3 *contract shall not maintain a drug formulary with more than four*
4 *tiers.*

5 (4) This section shall not be construed to limit a health care
6 service plan from placing any drug in a lower tier. *If a biologic*
7 *has a therapeutic equivalent, consistent with state law, it may be*
8 *placed on a tier other than tier four.*

9 (g) A health care service plan contract shall ensure that the
10 placement of prescription drugs on formulary tiers is based on
11 clinically indicated, reasonable medical management practices.

12 (h) (1) This section shall not be construed to require a health
13 care service plan to impose cost sharing. ~~This~~

14 (2) *This section shall not be construed to require cost sharing*
15 *for prescription drugs that state or federal law otherwise requires*
16 *to be provided without cost sharing.*

17 (3) *A plan's prescription drug benefit shall provide that if the*
18 *pharmacy's retail price for a prescription drug is less than the*
19 *applicable copayment or coinsurance amount, the enrollee shall*
20 *not be required to pay more than the retail price.*

21 ~~(i) This section does not require or authorize a health care~~
22 ~~service plan that contracts with the State Department of Health~~
23 ~~Care Services to provide services to Medi-Cal beneficiaries to~~
24 ~~provide coverage for prescription drugs that are not required~~
25 ~~pursuant to those programs or contracts, or to limit or exclude any~~
26 ~~prescription drugs that are required by those programs or~~
27 ~~contracts.~~ (j)

28 (i) In the provision of outpatient prescription drug coverage, a
29 health care service plan may utilize formulary, prior authorization,
30 step therapy, or other reasonable medical management practices
31 consistent with this

chapter. 32 (k)

33 (j) This section does not apply to a health care service plan that
34 contracts with the State Department of Health Care Services.

35 ~~(A) This section shall remain in effect only until January 1, 2020,~~
36 ~~and as of that date is repealed, unless a later enacted statute, that~~
37 ~~is enacted before January 1, 2020, deletes or extends that date.~~

38 SEC. 2. Section 1342.71 of the Health and Safety Code, as
39 added by Section 2 of Chapter 619 of the Statutes of 2015, is
40 repealed.

1 ~~1342.71. (a) The Legislature hereby finds and declares all of~~
2 ~~the following:~~
3 ~~(1) The federal Patient Protection and Affordable Care Act, its~~
4 ~~implementing regulations and guidance, and related state law~~
5 ~~prohibit discrimination based on a person's expected length of life,~~
6 ~~present or predicted disability, degree of medical dependency,~~
7 ~~quality of life, or other health conditions, including benefit designs~~
8 ~~that have the effect of discouraging the enrollment of individuals~~
9 ~~with significant health needs.~~
10 ~~(2) The Legislature intends to build on existing state and federal~~
11 ~~law to ensure that health coverage benefit designs do not have an~~
12 ~~unreasonable discriminatory impact on chronically ill individuals,~~
13 ~~and to ensure affordability of outpatient prescription drugs.~~
14 ~~(3) Assignment of all or most prescription medications that treat~~
15 ~~a specific medical condition to the highest cost tiers of a formulary~~
16 ~~may effectively discourage enrollment by chronically ill~~
17 ~~individuals, and may result in lower adherence to a prescription~~
18 ~~drug treatment regimen.~~
19 ~~(b) A nongrandfathered health care service plan contract that is~~
20 ~~offered, amended, or renewed on or after January 1, 2017, shall~~
21 ~~comply with this section.~~
22 ~~(c) A health care service plan contract that provides coverage~~
23 ~~for outpatient prescription drugs shall cover medically necessary~~
24 ~~prescription drugs, including nonformulary drugs determined to~~
25 ~~be medically necessary consistent with this chapter.~~
26 ~~(d) (1) Consistent with federal law and guidance, the formulary~~
27 ~~or formularies for outpatient prescription drugs maintained by the~~
28 ~~health care service plan shall not discourage the enrollment of~~
29 ~~individuals with health conditions and shall not reduce the~~
30 ~~generosity of the benefit for enrollees with a particular condition~~
31 ~~in a manner that is not based on a clinical indication or reasonable~~
32 ~~medical management practices. Section 1342.7 and any regulations~~
33 ~~adopted pursuant to that section shall be interpreted in a manner~~
34 ~~that is consistent with this section.~~
35 ~~(2) For combination antiretroviral drug treatments that are~~
36 ~~medically necessary for the treatment of AIDS/HIV, a health care~~
37 ~~service plan contract shall cover a single-tablet drug regimen that~~
38 ~~is as effective as a multitablet regimen unless, consistent with~~
39 ~~clinical guidelines and peer-reviewed scientific and medical~~

1 ~~literature, the multitablet regimen is clinically equally or more~~
2 ~~effective and more likely to result in adherence to a drug regimen.~~

3 ~~(e) A health care service plan contract shall ensure that the~~
4 ~~placement of prescription drugs on formulary tiers is based on~~
5 ~~clinically indicated, reasonable medical management practices.~~

6 ~~(f) This section shall not be construed to require a health care~~
7 ~~service plan to impose cost sharing. This section shall not be~~
8 ~~construed to require cost sharing for prescription drugs that state~~
9 ~~or federal law otherwise requires to be provided without cost~~
10 ~~sharing.~~

11 ~~(g) This section does not require or authorize a health care~~
12 ~~service plan that contracts with the State Department of Health~~
13 ~~Care Services to provide services to Medi-Cal beneficiaries to~~
14 ~~provide coverage for prescription drugs that are not required~~
15 ~~pursuant to those programs or contracts, or to limit or exclude any~~
16 ~~prescription drugs that are required by those programs or contracts.~~

17 ~~(h) In the provision of outpatient prescription drug coverage, a~~
18 ~~health care service plan may utilize formulary, prior authorization,~~
19 ~~step therapy, or other reasonable medical management practices~~
20 ~~consistent with this chapter.~~

21 ~~(i) This section shall not apply to a health care service plan that~~
22 ~~contracts with the State Department of Health Care Services.~~

23 ~~(j) This section shall become operative on January 1, 2020.~~

24 SEC. 3. Section 10123.193 of the Insurance Code, as amended
25 by Section 204 of Chapter 86 of the Statutes of 2016, is amended
26 to read:

27 10123.193. (a) The Legislature hereby finds and declares all
28 of the following:

29 (1) The federal Patient Protection and Affordable Care Act, its
30 implementing regulations and guidance, and related state law
31 prohibit discrimination based on a person's expected length of life,
32 present or predicted disability, degree of medical dependency,
33 quality of life, or other health conditions, including benefit designs
34 that have the effect of discouraging the enrollment of individuals
35 with significant health needs.

36 (2) The Legislature intends to build on existing state and federal
37 law to ensure that health coverage benefit designs do not have an
38 unreasonable discriminatory impact on chronically ill individuals,
39 and to ensure affordability of outpatient prescription drugs.

1 (3) Assignment of all or most prescription medications that treat
2 a specific medical condition to the highest cost tiers of a formulary
3 may effectively discourage enrollment by chronically ill
4 individuals, and may result in lower adherence to a prescription
5 drug treatment regimen.

6 (b) A nongrandfathered policy of health insurance that is offered,
7 amended, or renewed on or after January 1, 2017, shall comply
8 with this section. The cost-sharing limits established by this section
9 apply only to outpatient prescription drugs covered by the policy
10 that constitute essential health benefits, as defined by
Section 11 10112.27.

12 (c) A policy of health insurance that provides coverage for
13 outpatient prescription drugs shall cover medically necessary
14 prescription drugs, including nonformulary drugs determined to
15 be medically necessary consistent with this part.

16 (d) Copayments, coinsurance, and other cost sharing for
17 outpatient prescription drugs shall be reasonable so as to allow
18 access to medically necessary outpatient prescription drugs.

19 (e) (1) Consistent with federal law and guidance, the formulary
20 or formularies for outpatient prescription drugs maintained by the
21 health insurer shall not discourage the enrollment of individuals
22 with health conditions and shall not reduce the generosity of the
23 benefit for insureds with a particular condition in a manner that is
24 not based on a clinical indication or reasonable medical
25 management practices. Section 1342.7 of the Health and Safety
26 Code and any regulations adopted pursuant to that section shall
27 be interpreted in a manner that is consistent with this section.

28 (2) For combination antiretroviral drug treatments that are
29 medically necessary for the treatment *or prevention* of AIDS/HIV,
30 a policy of health insurance shall cover a single-tablet drug regimen
31 that is as effective as a multitablet regimen unless, consistent with
32 clinical guidelines and peer-reviewed scientific and medical
33 literature, the multitablet regimen is clinically equally or more
34 effective and more likely to result in adherence to a drug regimen.

35 (3) Any limitation or utilization management shall be consistent
36 with and based on clinical guidelines and peer-reviewed scientific
37 and medical literature.

38 (f) (1) With respect to an individual or group policy of health
39 insurance subject to Section 10112.28, the copayment, coinsurance,
40 or any other form of cost sharing for a covered outpatient

1 prescription drug for an individual prescription for a supply of up
2 to 30 days shall not exceed two hundred fifty dollars (\$250), except
3 as provided in paragraphs (2) and (3).

4 (2) With respect to products with actuarial value at or equivalent
5 to the bronze level, cost sharing for a covered outpatient
6 prescription drug for an individual prescription for a supply of up
7 to 30 days shall not exceed five hundred dollars (\$500), except as
8 provided in paragraph (3).

9 (3) For a policy of health insurance that is a “high deductible
10 health plan” under the definition set forth in Section 223(c)(2) of
11 Title 26 of the United States Code, paragraphs (1) and (2) of this
12 subdivision applies only once an insured’s deductible has been
13 satisfied for the year.

14 (4) For a nongrandfathered individual or small group policy of
15 health insurance, the annual deductible for outpatient drugs, if any,
16 shall not exceed twice the amount specified in paragraph (1) or
17 (2), respectively.

18 (5) For purposes of paragraphs (1) and (2), “any other form of
19 cost sharing” shall not include a deductible.

20 (g) (1) If a policy of health insurance offered, sold, or renewed
21 in the nongrandfathered individual or small group market maintains
22 a drug formulary grouped into tiers that includes a fourth tier, a
23 policy of health insurance shall use the following definitions for
24 each tier of the drug formulary:

25 (A) Tier one shall consist of most generic drugs and low-cost
26 preferred brand name drugs.

27 (B) Tier two shall consist of nonpreferred generic drugs,
28 preferred brand name drugs, and any other drugs recommended
29 by the health insurer’s pharmacy and therapeutics committee based
30 on safety, efficacy, and cost.

31 (C) Tier three shall consist of nonpreferred brand name drugs
32 or drugs that are recommended by the health insurer’s pharmacy
33 and therapeutics committee based on safety, efficacy, and cost, or
34 that generally have a preferred and often less costly therapeutic
35 alternative at a lower tier.

36 (D) Tier four shall consist of drugs that are biologics, drugs that
37 the FDA or the manufacturer requires to be distributed through a
38 specialty pharmacy, drugs that require the insured to have special
39 training or clinical monitoring for self-administration, or drugs

1 that cost the health insurer more than six hundred dollars (\$600)
2 net of rebates for a one-month supply.

3 (2) In placing specific drugs on specific tiers, or choosing to
4 place a drug on the formulary, the insurer shall take into account
5 the other provisions of this section and this part.

6 (3) A policy of health insurance may maintain a drug formulary
7 with fewer than four tiers. *A policy of health insurance shall not*
8 *maintain a drug formulary with more than four tiers.*

9 (4) This section shall not be construed to limit a health insurer
10 from placing any drug in a lower tier. *If a biologic has a*
11 *therapeutic equivalent, consistent with state law, it may be placed*
12 *on a tier other than tier four.*

13 (h) (1) This section shall not be construed to require a health
14 insurer to impose cost sharing. ~~This~~

15 (2) *This section shall not be construed to require cost sharing*
16 *for prescription drugs that state or federal law otherwise requires*
17 *to be provided without cost sharing.*

18 (3) *A prescription drug benefit shall provide that if the*
19 *pharmacy's retail price for a prescription drug is less than the*
20 *applicable copayment or coinsurance amount, the insured shall*
21 *not be required to pay more than the retail price.*

22 (i) A policy of health insurance shall ensure that the placement
23 of prescription drugs on formulary tiers is based on clinically
24 indicated, reasonable medical management practices.

25 (j) In the provision of outpatient prescription drug coverage, a
26 health insurer may utilize formulary, prior authorization, step
27 therapy, or other reasonable medical management practices
28 consistent with this part.

29 ~~(k) This section shall remain in effect only until January 1, 2020,~~
30 ~~and as of that date is repealed, unless a later enacted statute, that~~
31 ~~is enacted before January 1, 2020, deletes or extends that date.~~

32 SEC. 4. Section 10123.193 of the Insurance Code, as added
33 by Section 8 of Chapter 619 of the Statutes of 2015, is repealed.

34 ~~10123.193. (a) The Legislature hereby finds and declares all~~
35 ~~of the following:~~

36 ~~(1) The federal Patient Protection and Affordable Care Act, its~~
37 ~~implementing regulations and guidance, and related state law~~
38 ~~prohibit discrimination based on a person's expected length of life,~~
39 ~~present or predicted disability, degree of medical dependency,~~
40 ~~quality of life, or other health conditions, including benefit designs~~

1 ~~that have the effect of discouraging the enrollment of individuals~~
2 ~~with significant health needs.~~

3 ~~(2) The Legislature intends to build on existing state and federal~~
4 ~~law to ensure that health coverage benefit designs do not have an~~
5 ~~unreasonable discriminatory impact on chronically ill individuals,~~
6 ~~and to ensure affordability of outpatient prescription drugs.~~

7 ~~(3) Assignment of all or most prescription medications that treat~~
8 ~~a specific medical condition to the highest cost tiers of a formulary~~
9 ~~may effectively discourage enrollment by chronically ill~~
10 ~~individuals, and may result in lower adherence to a prescription~~
11 ~~drug treatment regimen.~~

12 ~~(b) A nongrandfathered policy of health insurance that is offered,~~
13 ~~amended, or renewed on or after January 1, 2017, shall comply~~
14 ~~with this section.~~

15 ~~(c) A policy of health insurance that provides coverage for~~
16 ~~outpatient prescription drugs shall cover medically necessary~~
17 ~~prescription drugs, including nonformulary drugs determined to~~
18 ~~be medically necessary consistent with this part.~~

19 ~~(d) Copayments, coinsurance, and other cost sharing for~~
20 ~~outpatient prescription drugs shall be reasonable so as to allow~~
21 ~~access to medically necessary outpatient prescription drugs.~~

22 ~~(e) (1) Consistent with federal law and guidance, the formulary~~
23 ~~or formularies for outpatient prescription drugs maintained by the~~
24 ~~health insurer shall not discourage the enrollment of individuals~~
25 ~~with health conditions and shall not reduce the generosity of the~~
26 ~~benefit for insureds with a particular condition in a manner that is~~
27 ~~not based on a clinical indication or reasonable medical~~
28 ~~management practices. Section 1342.7 of the Health and Safety~~
29 ~~Code and any regulations adopted pursuant to that section shall~~
30 ~~be interpreted in a manner that is consistent with this section.~~

31 ~~(2) For combination antiretroviral drug treatments that are~~
32 ~~medically necessary for the treatment of AIDS/HIV, a policy of~~
33 ~~health insurance shall cover a single-tablet drug regimen that is as~~
34 ~~effective as a multitablet regimen unless, consistent with clinical~~
35 ~~guidelines and peer-reviewed scientific and medical literature, the~~
36 ~~multitablet regimen is clinically equally or more effective and~~
37 ~~more likely to result in adherence to a drug regimen.~~

38 ~~(3) Any limitation or utilization management shall be consistent~~
39 ~~with and based on clinical guidelines and peer-reviewed scientific~~
40 ~~and medical literature.~~

1 ~~(f) This section shall not be construed to require a health insurer~~
2 ~~to impose cost sharing. This section shall not be construed to~~
3 ~~require cost sharing for prescription drugs that state or federal law~~
4 ~~otherwise requires to be provided without cost sharing.~~

5 ~~(g) A policy of health insurance shall ensure that the placement~~
6 ~~of prescription drugs on formulary tiers is based on clinically~~
7 ~~indicated, reasonable medical management practices.~~

8 ~~(h) In the provision of outpatient prescription drug coverage, a~~
9 ~~health insurer may utilize formulary, prior authorization, step~~
10 ~~therapy, or other reasonable medical management practices~~
11 ~~consistent with this part.~~

12 ~~(i) This section shall become operative on January 1, 2020.~~

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

APPENDIX B PREP AND PEP GUIDELINES

Figure 8. USPHS Recommended Oral PrEP Medications, 2014

Generic Name	Trade Name	Dose	Frequency	Common Side Effects ⁶⁶
Tenofovir disoproxil fumarate (TDF)	Viread	300 mg	Once a day	Nausea, flatulence
Emtricitabine (FTC) ^a	Emtriva	200 mg	Once a day	Rash, headache
TDF + FTC	Truvada	300mg/200 mg	Once a day	—

^aNot recommended alone; only for use in combination with TDF.
 Source: USPHS, 2014.

Figure 9. USPHS Preferred and Alternative HIV Postexposure Prophylaxis Regimens for Occupational Exposure to HIV, 2013

PREFERRED HIV PEP REGIMEN	
Raltegravir (Isentress [®] ; RAL) 400mg PO Twice Daily Plus Truvada [™] , 1 PO Once Daily [Tenofovir DF (Viread [®] ; TDF) 300mg + emtricitabine (Emtriva [™] ; FTC) 200mg]	
ALTERNATIVE REGIMENS	
(May combine one drug or drug pair from the left column with 1 pair of nucleoside/nucleotide reverse transcriptase inhibitors from the right column. Prescribers unfamiliar with these agents/regimens should consult physicians familiar with the agents and their toxicities.) ^{*,^}	
Raltegravir (Isentress [®] ; RAL)	Tenofovir DF (Viread [®] ; TDF) + emtricitabine (Emtriva [™] ; FTC); available as Truvada [™]
Darunavir (Prezista [®] ; DRV) + ritonavir (Norvir [®] ; RTV)	Tenofovir DF (Viread [®] ; TDF) + lamivudine (Epivir [®] ; 3TC)
Etravirine (Intenceo [®] ; ETR)	Zidovudine (Retrovir [®] ; ZDV; AZT) + lamivudine (Epivir [®] ; 3TC); available as Combivir [®]
Rilpivirine (Edurant [™] ; RPV)	Zidovudine (Retrovir [®] ; ZDV; AZT) + emtricitabine (Emtriva [™] ; FTC)
Atazanavir (Reyataz [®] ; ATV) + ritonavir (Norvir [®] ; RTV)	
Lopinavir/ritonavir (Kaletra [®] ; LPV/RTV)	
The following alternative is a complete fixed-dose combination regimen and no additional antiretrovirals are needed: Stribild [™] (elvitegravir, cobicistat, tenofovir DF, emtricitabine)	
ALTERNATIVE ANTIRETROVIRAL AGENTS FOR USE AS PEP ONLY WITH EXPERT CONSULTATION[^]	
Abacavir (Ziagen [®] ; ABC)	
Efavirenz (Sustiva [®] ; EFV)	
Enfuvirtide (Fuzeon [™] ; T20)	
Fosamprenavir (Lexiva [®] ; FOSAPV)	
Maraviroc (Selzentry [®] ; MVC)	
Saquinavir (Invirase [®] ; SQV)	
Stavudine (Zerit [®] ; d4T)	
ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP	
Didanosine (Videx EC [®] ; ddI)	
Nelfinavir (Viracept [®] ; NFV)	
Tipranavir (Aptivus [®] ; TPV)	
ANTIRETROVIRAL AGENTS CONTRAINDICATED AS PEP	
Nevirapine (Viramune [®] ; NVP)	

--- For consultation or assistance with HIV PEP, contact PEPline at telephone 888-448-4911 or visit their website http://www.nccc.ucsf.edu/about_nccc/pepline/. DF, didanosine fumarate; PO, per os.

*The alternatives regimens are listed in order of preference, however, other alternatives may be reasonable based upon patient and clinician preference.

[^]For Drug Dosing Information, see Appendix B

Source: Kuhar et al., 2013.

Figure 10. CDC Preferred and Alternative PEP Therapies for Non-Occupational Exposure to HIV

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	Preferred	A 3-drug regimen consisting of tenofovir DF 300 mg <i>and</i> fixed dose combination emtricitabine 200 mg (Truvada [®]) once daily <i>with</i> raltegravir 400 mg twice daily <i>or</i> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg <i>and</i> fixed dose combination emtricitabine 200 mg (Truvada) once daily <i>with</i> darunavir 800 mg (as 2, 400-mg tablets) once daily <i>and</i> ritonavir [®] 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤ 59 mL/min)	Preferred	A 3-drug regimen consisting of zidovudine <i>and</i> lamivudine, with both doses adjusted to degree of renal function <i>with</i> raltegravir 400 mg twice daily <i>or</i> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine <i>and</i> lamivudine, with both doses adjusted to degree of renal function <i>with</i> darunavir 800 mg (as 2, 400-mg tablets) once daily <i>and</i> ritonavir [®] 100 mg once daily
Children aged 2–12 years	Preferred	A 3-drug regimen consisting of tenofovir DF, emtricitabine, and raltegravir, with each drug dosed to age and weight ^d
	Alternative	A 3-drug regimen consisting of zidovudine <i>and</i> lamivudine <i>with</i> raltegravir <i>or</i> lopinavir/ritonavir [®] , with raltegravir and lopinavir/ritonavir dosed to age and weight ^d
	Alternative	A 3-drug regimen consisting of tenofovir DF <i>and</i> emtricitabine <i>and</i> lopinavir/ritonavir [®] , with each drug dosed to age and weight ^d

Age group	Preferred/ alternative	Medication
Children aged 3–12 years	Alternative	A 3-drug regimen consisting of tenofovir DF and emtricitabine and darunavir ^c /ritonavir ^b , with each drug dosed to age and weight ^d
Children aged 4 weeks ^e –<2 years	Preferred	A 3-drug regimen consisting of zidovudine oral solution <i>and</i> lamivudine oral solution <i>with</i> raltegravir <i>or</i> lopinavir/ritonavir ^b oral solution (Kaletra ^a), with each drug dosed to age and weight ^d
Children aged 4 weeks ^e –<2 years	Alternative	A 3-drug regimen consisting of zidovudine oral solution <i>and</i> emtricitabine oral solution <i>with</i> raltegravir <i>or</i> lopinavir/ritonavir ^b oral solution (Kaletra), with each drug adjusted to age and weight ^d
Children aged birth–27 days	Consult a pediatric HIV-specialist	
<p>Abbreviations: HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.</p> <p>^a These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.</p> <p>^b Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active against HIV in the above “3-drug” regimens.</p> <p>^c Gilead Sciences, Inc., Foster City, California.</p> <p>^d See also Table 6.</p> <p>^e Darunavir only FDA-approved for use among children aged ≥3 years.</p> <p>^f Children should have attained a postnatal age of ≥28 days and a postmenstrual age (i.e., first day of the mother’s last menstrual period to birth plus the time elapsed after birth) of ≥42 weeks.</p> <p>^g AbbVie, Inc., North Chicago, Illinois.</p>		

Source: CDC, 2016.

APPENDIX C LITERATURE REVIEW METHODS

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

Methods for Literature Review on Medications to Prevent HIV/AIDS

Studies of the effectiveness and potential harms of medications for HIV prevention were identified through searches of PubMed, the Cochrane Library, AIDSInfo, and Web of Science. 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 for literature on PrEP was initially limited to studies published from 2010 to present as CHBRP had identified existing systematic review published in 2012 by the Cochrane Review. However, during review, CHBRP identified a more recent systematic review published in 2016; therefore, literature returned from the initial search of PrEP-related search was reviewed from 2015 to the present. Similarly, CHBRP identified a 2014 review of PEP literature, which, in addition to several smaller supplementary reviews, forms the basis of the evidence review for PEP.

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.

Of the 1,200 articles found in the literature search, 83 were reviewed for potential inclusion in this report on SB 1021, and a total of 26 studies were included in the medical effectiveness review for HIV prevention therapies. The other articles were eliminated because they did not focus on therapies for HIV prevention, were of poor quality, or did not report findings from clinical research studies.

Methods for Literature Review on Cost Sharing and Prescription Drug Use

Studies of the effects of cost sharing on use of prescription drugs were identified through searches of the Cochrane Library, EconLit, Google Scholar, PubMed, and Web of Science. The search was limited to abstracts of peer-reviewed research studies that were published in English, conducted in the United States, and published from 2015 to present. For studies published prior to 2014, CHBRP relied on a literature search conducted in 2015 for its analysis of AB 339, which established the cost-sharing statutes that are amended by SB 1021. Since SB 1021 only amends selected elements of the law established by AB 339, CHBRP limited the evidence review to recent literature that broadly pertains to the impacts of cost sharing on outpatient prescription drug use and adherence. Of the 83 articles found in the literature review, 11 were reviewed for potential inclusion in this report on SB 1021, and a total of two studies were included in the medical effectiveness review for cost sharing impacts on prescription drug use. The other articles were eliminated because they did not focus on the impacts of cost sharing on prescription drug use, were of poor quality, or did not report findings from clinical research studies.

The current review focused on studies conducted in the United States because findings from studies of cost sharing in countries with different types of health care systems may not be generalizable to the U.S. in general and to California in particular. The majority of CHBRP's analysis relies on three systematic reviews and additional smaller studies on cost sharing.

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.

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*.³⁴ 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.

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.

³⁴ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

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.

Search Terms (* indicates truncation of word stem)

PubMed

MeSH terms:

- HIV Infections/prevention and control [Majr]
- HIV Infections/economics
- HIV Infections/epidemiology
- HIV Infections/statistics and numerical data
- Pre-Exposure Prophylaxis
- Post-Exposure Prophylaxis
- Emtricitabine, Tenofovir Disoproxil Fumarate Drug Combination
- Zidovudine/administration and dosage
- African Americans
- Continental Population Groups
- Cost Sharing
- Costs and Cost Analysis
- Deductibles and Coinsurance
- Drug Costs
- Drug Prescriptions/economics
- Drug Utilization
- Health Insurance Exchanges
- Insurance, Health
- Insurance, Health, Reimbursement
- Insurance, Pharmaceutical Services

- Medicaid
- Medicare Part D
- Medication Therapy Management
- Prescription Drugs/economics
- Prescription Fees
- Sexual and Gender Minorities

EMBASE Descriptors:

- Ancestry Group/exp
- Cost/exp
- Drug Cost/exp
- Emtricitabine Plus Tenofovir Disoproxil/exp
- Health Care Access/exp
- Health Care Cost/exp
- Human Immunodeficiency Virus Infection/exp/mj/prevention and control
- Post Exposure Prophylaxis/exp
- Pre-exposure Prophylaxis/exp
- Prescription/exp
- Reimbursement/exp
- Zidovudine/exp

Keywords:

- Coinsurance
- Copay
- Copayment
- Cost Savings
- Deductibles
- Demand
- Economic Loss
- Epidemiology
- Formulary
- Gender
- Incidence
- Outcomes
- Premature Death
- Prevalence
- Price
- Productivity
- Raltegravir
- Reimbursement
- Retail Price
- Retrovir
- Truvada
- Utilization

APPENDIX D COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm PricewaterhouseCoopers (PwC).³⁵

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.³⁶

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

Analysis-Specific Caveats and Assumptions

Medications to Prevent HIV/AIDS

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of SB 1021's provision regarding the coverage of medications for the prevention of HIV/AIDS.

The population subject to the mandated offering includes enrollees in DMHC-regulated plans and CDI-regulated policies for large-group, small-group, and individual marketplace plans, and CalPERS plans. Enrollees associated with Medi-Cal are not subject to the HIV/AIDS treatment and prevention coverage requirement.

Baseline HIV prevention drug treatment costs and associated utilization were based on 2016 MarketScan® commercial claims and enrollment data for the state of California. Since the potential impact change of this mandate affects those enrollees who use HIV drug for prevention purposes, the analysis was limited to enrollees that had not been diagnosed with HIV as of the date of the first HIV prevention drug usage in 2016.

- CHBRP assumes that if an individual is diagnosed as HIV positive, he/she cannot become HIV negative in the future. This is done because some of the HIV prevention drugs are also used by HIV positive enrollees for treatment purposes.
- CHBRP expects that any mandate utilization changes from this component of the bill would be based on changes to current HIV prevention coverage.
- CHBRP expects that the cost per prescription remains the same between premandate and postmandate.
- CHBRP assumes that the mandate would not impact any forms of member cost sharing, such as deductibles, copays, and coinsurance.
- CHBRP also assumed that the bill would not affect utilization management techniques that may impact the utilization of medical and drug treatments between baseline and post mandate periods, such as use of prior authorization requirements and medical review for medical

³⁵ CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

³⁶ See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

treatments, and use of formularies, tiered copayments, or mandatory generic substitutions for drug treatments.

- While it is possible that SB 1021 has an indirect effect on utilization by increasing the awareness of PrEP, it is unclear to what degree the bill would increase awareness, and how that awareness would change provider behavior, and change consumer awareness and demand for PrEP.

The following table lists the diagnosis codes used to identify HIV positive enrollees and drug product names used to identify HIV prevention drugs.

Prevention treatment of HIV used Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes identified with carrier coverage guidelines and reviewed by a content expert. Additionally, drug prevention treatment of HIV used National Drug Codes (NDC) codes identified using the Truven Health Analytics Red Book™ and reviewed by a content expert.

Table 8. Diagnosis Codes

Diagnosis Codes (ICD 9 and ICD-10)	Deion
B20	HIV Disease
042	HIV Disease

Table 9. List of Medications to Prevent HIV

HIV Prevention Category	Drug Product Name
Pre-HIV Exposure / Post-HIV Exposure	Truvada
Post-HIV Exposure	Darunavir
Post-HIV Exposure	Dolutegravir
Post-HIV Exposure	Raltegravir
Post-HIV Exposure	Ritonavir
Post-HIV Exposure	Zidovudine

HIV prevention drug treatment users were categorized as pre-HIV exposure (PrEP) prevention and post-HIV exposure prevention (PEP). The PrEP exposure regimen is a single-tab Truvada® pill daily. The acute PEP prescription is a 28-day regimen of multitablet combination of NRTIs and integrase inhibitors. One or more of the post-HIV exposure drugs can also be used for acute exposure treatment. The majority of providers prescribe multi-drug PEP for all exposures (guidelines generally suggest that more than one of the post-HIV exposure drugs should be used, e.g., Truvada plus another drug), however clinicians experienced in PEP management may on occasion prescribe a modified regimen (e.g., Truvada only for PEP for lower risk exposure). Because Truvada-only is rarely used for PEP, CHBRP assumed Truvada-only users observed in the MarketScan dataset were PrEP exposure prevention treatment users. If an HIV-negative enrollee uses at least one of the post-HIV exposure exclusive drugs (not Truvada), that user is considered a post-exposure user for the remainder of the year. Another post-exposure prevention strategy addresses fetal exposure during pregnancy and birth. In general, this requires the baby receive a 4- to 6-week course of Zidovudine, which is on occasion (but rarely) used in combination with another drug.

Baseline unit costs were trended at an annual rate 13.7% per year from 2016 to 2019 based on the “2017 Drug Trend Report” by Express Scripts. The 13.7% trend represents the 2017 HIV drug trends for the commercial population represented within the report. The analysis assumes that the unit cost per drug does not change postmandate.

The analysis assumed that utilization rates per 1,000 enrollees change postmandate only due to increased coverage. Baseline utilization rates per 1,000 were developed based on MarketScan data for members not diagnosed with HIV and who also use the HIV prevention drugs.

Carrier surveys were administered to estimate the percentage of enrollees who had HIV- outpatient drug prevention coverage. Results from the CHBRP current coverage questionnaire for health plans and insurers indicate 100% on-formulary coverage for HIV PrEP and PEP, respectively. Therefore, no additional utilization changes were modeled.

Medications to Prevent HIV/AIDS – Benefit Coverage, Utilization and Cost

CHBRP found 100% of enrollees have coverage for medications to prevent HIV/AIDS. As part of its analysis of this provision, CHBRP examined utilization and cost of medications to prevent HIV/AIDS in MarketScan data. Findings are shown in Table 10.

Table 10. 2019 Impacts of SB 1021’s Provision to Cover Medications to Prevent HIV/AIDS on Benefit Coverage, Utilization, and Cost

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates ^(a)	23,433,000	23,433,000	0	0%
Total enrollees with health insurance subject to SB 1021’s provision to cover medications to prevent HIV/AIDS	15,923,000	15,923,000	0	0%
Number of enrollees with health insurance fully compliant with SB 1021’s provision to cover medications to prevent HIV/AIDS	15,923,000	15,923,000	0	0%
Percent of enrollees with coverage for medications to prevent HIV/AIDS	100%	100%	0	0%
Utilization and unit cost				
Number of Enrollees Using:				
HIV Prevention Treatment Drugs – PrEP	23,267	23,267	0	0%
HIV Prevention Treatment Drugs – PEP	6,708	6,708	0	0%
HIV Prevention Treatment Drugs – PrEP and PEP	29,975	29,975	0	0%
Average Cost / Script (Based on 30-Day Supply):				
HIV Prevention Treatment Drugs – PrEP	\$2,220	\$2,220	0	0%
HIV Prevention Treatment Drugs – PEP (b)	\$2,000	\$2,000	0	0%
HIV Prevention Treatment Drugs – PrEP and PEP	\$2,167	\$2,167	0	0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, and Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance. (b) PEP cost represents the average allowed cost of the combination of multiple drugs that are prescribed for post-exposure preventive treatment.

Key: PrEP= pre-exposure prophylaxis; PEP=post-exposure prophylaxis

Outpatient Drug Cost-Sharing Limits

This subsection discusses the caveats and assumptions relevant specifically to the projection analysis of SB 1021's provision regarding the cost-sharing limits.

CHBRP used the 2016 California MarketScan outpatient prescription drug data. For the 2016 base year, CHBRP normalized the allowed cost (per prescription) to a 30-day prescription. That is, for prescription lines with more than a 30-day supply, CHBRP adjusted the allowed cost to represent the cost for a 30-day prescription supply. Allowed cost for prescriptions of less than 30 days were left unchanged. For the 2016 base year, cost sharing was calculated as the sum of any coinsurance, copayments, and deductible amounts. Cost sharing was also normalized to a 30-day prescription (similar to the allowed cost normalization method). CHBRP calculated 30-day "normalized" allowed cost from 2017 to 2021, respectively, by applying a 11% annual specialty unit cost trend to each prescription cost based on "2016 Drug Trend Report" by Express Scripts and actuarial judgment (see Table 5, which shows unit cost trend for the Top 25 specialty drugs based on total spend for the commercial population — weighted average trend for the top 25 is around 11%). Cost sharing was kept at the 2016 levels through this entire analysis.

CHBRP compiled lists, by prescription drug product name, of drugs that would hit the \$625 specialty drug rule by prescription line, based on that particular year's projected allowed costs (normalized to 30-day prescription). This spend rule was identified as the drug cost that would trigger hitting the cost-sharing limits as outlined in AB 339 and maintained by SB 1021. The individual drug lists were sorted by total annual allowed spend that is subject by the \$625 spend rule. The 2016 drug list contains 1,384 distinct drugs that with at least one with \geq \$625 allowed cost. The 2021 drug lists increases to 1,964 distinct drugs with at least one prescription with \geq \$625 allowed cost. Any differences/increase in drug types (and allowed costs) between 2016 to 2021 is due to the following: (a) New drugs become subject to the specialty drug categorization. CHBRP is trending future drug prices at by 11% annually. Therefore, a prescription that was allowed cost of \$600 in year 2016 would not show up on the 2016 list but would show up on the list (and allowed cost columns) for years 2017 through 2021. (b) There is variation in the allowed cost for a given drug. More prescriptions of drugs that were captured on the 2016 list appear in 2021 since some of the prescription for that drugs were previously under \$625 in 2016, but by 2021 the allowed cost per prescription for those prescriptions rise above the specialty price threshold.

Enrollees were determined to hit the cost-sharing limit in years 2016 to 2021 if their 2016 30-day normalized cost sharing amounts were at least \$250 per prescription line. The range of distinct enrollees who might to hit the cost-sharing limit is as follows: 63,078 in 2016 to 128,344 in 2021. Total 2016 California enrollment in the MarketScan data is 1,862,814. The number of enrollees subject to the SB 1021 mandate in California is 15,923,000. The percent of enrollees in California subject to the mandate who could potentially hit the cost-sharing limit increases from 5% in 2019 to about 7% in 2021. Because CHBRP assumes all enrollees in a bronze equivalent plan in the projection analysis, the projection estimates provided are the **maximum** number of enrollees who may hit the cost-sharing limit (i.e., upper limit). The likely number of enrollees hitting the limit would be lower given not all enrollees would be in a bronze equivalent plan.

CHBRP found that for the majority of high-cost specialty drugs identified for year 2016, the associated copayments and/or co-insurance amounts are relatively low. CHBRP considered copayments to be "low" if the copay per prescription was \leq \$50 (no normalization for a 30-day prescription was applied). Coinsurance was considered "low" if the coinsurance per prescription was \leq \$100 (no normalization for a

30-day prescription was applied). No member cost is where there is no copayment or co-insurance for the enrollee.

Table 11. Copayment and Co-insurance for Specialty Drugs

	Copayment <=\$50 per prescription	Co-insurance <=\$100 per prescription)	No Copay or Co- insurance (copayment and co-insurance <=\$0 per prescription)
Top 25 Specialty Drugs	70.4%	90.6%	12.8%
All Specialty Drugs	75.5%	91.3%	17.6%

Source: California Health Benefits Review Program, 2018. Analysis of 2016 MarketScan claims data.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 1021 would mandate. Considering the criteria specified by CHBRP’s authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares 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.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for prescription treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently 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 carriers 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.

APPENDIX E OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table 12, for 2019, CHBRP estimates that approximately 1.4% of enrollees in plans regulated by DMHC or policies regulated by CDI have no coverage for outpatient prescription drugs (OPDs) and 3.0% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

Table 12. 2019 Outpatient Prescription Drug Coverage

Enrollees in DMHC-Regulated Plans and CDI-Regulated Policies	
Enrollee Counts	
Total enrollees in plans/policies subject to state Mandates ^(a)	23,433,000
Outpatient Prescription Drug (OPD) Coverage	
DMHC- or CDI-regulated brand-name and generic OPD coverage	95.5%
DMHC- or CDI-regulated generic-only coverage	0.1%
No OPD coverage	1.4%
Other OPD coverage	3.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organization; OPD = Outpatient Prescription Drug.

Additional detail about the presence and absence of OPD coverage in various market segments is presented below, in Table 13, Table 14, and Table 15.

Relevant State and Federal Law

- A number of overlapping state and federal laws require broad OPD coverage or coverage for particular drugs, but the requirements are not applicable to all forms of health insurance.
- Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for Essential Health Benefits (EHBs).³⁷
- Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.³⁸

³⁷ California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA

³⁸ California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA

- Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.³⁹

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

Presence or Absence of Coverage for Outpatient Prescription Drugs and Related Regulation

Coverage of OPDs was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the largest providers of health insurance in California. Responses to this survey represent 95% of enrollees in these markets. The California Public Employees' Retirement System (CalPERS) was queried regarding coverage among DMHC regulated plan enrollees associated with CalPERS. The California Department of Health Care Services (DHCS) was queried about coverage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have coverage for OPDs through their DMHC-regulated plan or CDI-regulated policy. These enrollee's OPD coverage is generally accessed through the enrollee's "pharmacy benefit," and generally used when acquiring drugs at an outpatient pharmacy or mail order service. When OPD coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As coverage for OPDs is not universally required, some enrollees in DMHC-regulated plans and CDI-regulated policies have no OPD coverage. Although these enrollee's health insurance cover prescription drugs delivered during a hospital (or other facility) admission and some prescription drugs that are dispensed through a clinician's office, these enrollees' health insurance would not generally help them acquire drugs intended for outpatient use. As noted above, there are some drug specific exceptions, such as insulin, but coverage would be limited to those specific outpatient drugs.

In terms of alternate regulation, some enrollees who have no OPD benefit through their DMHC-regulated plan or CDI-regulated policy still do have an OPD benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large-group plan to exclude coverage for OPDs and then contracts separately with a PBM to administer an OPD benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates.

³⁹ California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61

Table 13. 2019 Outpatient Prescription Drug Coverage in the Large Group and Publicly Funded Markets

	DMHC-Regulated Plans					CDI-Regulated Policies	
	Privately Funded Large Group		Publicly Funded Plans			Privately Funded Large Group	
	Grand-fathered	Nongrand-fathered	CalPERS HMOs ^(a)	MCMC (Under 65) ^(b)	MCMC (65+) ^(b)	Grandfathered	Nongrand-fathered
Enrollee Counts							
Total enrollees in plans/policies subject to state mandates (c)	1,860,000	7,511,000	887,000	6,832,000	678,000	5,000	209,000
Outpatient Prescription Drug (OPD) Coverage							
DMHC- or CDI-regulated brand-name and generic OPD coverage	95.9%	90.5%	79.5%	100.0%	100.0%	80.3%	86.8%
DMHC- or CDI-regulated generic-only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	3.8%	3.0%	0.0%	0.0%	0.0%	14.9%	2.2%
Other OPD coverage	0.3%	6.5%	20.5%	0.0%	0.0%	4.8%	11.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(b) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

Table 14. 2019 Outpatient Prescription Drug Coverage in the DMHC-regulated Small-Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	Nongrand-fathered Covered California ^(a)	Nongrand-fathered Mirror Plans ^(b)	Other Nongrand-fathered	Grand-fathered	Nongrand-fathered Covered California ^(a)	Nongrand-fathered Mirror Plans ^(b)	Other Nongrand-fathered
Enrollee Counts								
Total enrollees in plans/policies subject to state mandates ^(c)	355,000	49,000	687,000	2,026,000	103,000	1,157,000	611,000	210,000
Outpatient Prescription Drug (OPD) Coverage								
DMHC-regulated brand-name and generic OPD coverage	99.9%	100.0%	100.0%	100.0%	90.7%	100.0%	100.0%	100.0%
DMHC-regulated generic-only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	0.0%	0.0%	0.0%	0.0%	9.3%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

Table 15. 2019 Outpatient Prescription Drug Coverage in CDI-regulated Small-Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	Nongrand-fathered Covered California ^(a)	Nongrand-fathered Mirror Plans ^(b)	Other Nongrand-fathered	Grand-fathered	Nongrand-fathered Covered California ^(a)	Nongrand-fathered Mirror Plans ^(b)	Other Nongrand-fathered
Enrollee Counts								
Total enrollees in plans/policies subject to state mandates (c)	1,000	3,000	23,000	106,000	186,000	3,000	22,000	26,000
Outpatient Prescription Drug (OPD) Coverage								
CDI-regulated brand-name and generic OPD coverage	96.5%	100.0%	100.0%	100.0%	50.9%	100.0%	100.0%	100.0%
CDI-regulated generic-only coverage	0.0%	0.0%	0.0%	0.0%	39.1%	0.0%	0.0%	0.0%
No OPD coverage	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

APPENDIX F INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by ViiV Healthcare and GlaxoSmithKline in February 2018.

Tjaden K and Laca G. Email communication on February 22, 2018. Comments in support of SB 1021.

Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **PricewaterhouseCoopers**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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**A small percentage of AJ Scheitler's time is available to
serve as a backup CHBRP staff resource.*

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Joy Melnikow, MD, MPH, and Shauna Durbin, MPH, both of the University of California, Davis, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. Joy Melnikow, MD, MPH, and Dominique Ritley, MPH, both of the University of California, Davis, prepared the public health impact analysis. Riti Shimkhada, PhD, of the University of California, Los Angeles prepared the cost impact analysis. Susan Maerki, MHSA, MAE, of PricewaterhouseCoopers, and supporting actuarial staff, provided actuarial analysis. Content experts, Jonathan Watanabe, PharmD, MS, PhD, BCGP, of the University of California, San Diego, and Jennifer Cocohoba, PharmD, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. Adara Citron, MPH, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Marilyn Stebbins, PharmD, of the University of California, San Francisco, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request. CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org.