California Health Benefits Review Program

Analysis of California Senate Bill 535
Biomarker Testing

A Report to the 2021–2022 California State Legislature

April 20, 2021

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings
Analysis of California Senate Bill 535 Biomarker Testing

Summary to the 2021–2022 California State Legislature, April 20, 2021

SUMMARY

The version of California Senate Bill (SB) 535 analyzed by CHBRP would prohibit individual and group plans and policies from requiring prior authorization for biomarker testing for enrollees with advanced or metastatic stage 3 or 4 cancer, and cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

In 2022, of the 21.9 million Californians enrolled in state-regulated health insurance, 13.9 million of them (35% of all Californians) would have insurance subject to SB 535.

Benefit Coverage: Approximately 31% of enrollees have benefit coverage that requires prior authorization for biomarker testing at baseline. Postmandate, 100% of enrollees would have benefit coverage of biomarker testing without prior authorization. SB 535 appears not to exceed essential health benefits (EHBs).

Medical Effectiveness: There is *insufficient evidence* regarding delays caused by prior authorization for biomarker testing; however, it is possible that prior authorization could exacerbate the delays to obtaining results of biomarker tests.

There is *insufficient evidence* that prior authorization for biomarker testing impacts cancer outcomes for individuals with metastatic or advanced stage 3 or 4 cancer. To the extent that prior authorization delays biomarker testing, it could delay initiation of targeted therapies, which could increase mortality among persons with cancers for which targeted therapies are available.

Cost and Health Impacts[1]: In 2022, SB 535 would result in 5,160 additional enrollees receiving biomarker testing without prior authorization, for an additional $2,506,000 in annual expenditures. While the removal of prior authorization has the potential to decrease time to treatment, there is no evidence that evaluates this directly. Should SB 535 result in fewer delays in obtaining biomarker test results, it stands to reason there is the potential for a limited public health impact.

CHBRP did find evidence of disparities in rates of biomarker testing by income, with people of lower socio-economic levels receiving biomarker testing at lower rates. SB 535 could result in a reduction of income and racial/ethnic disparities in biomarker testing rates due to a decrease in coverage denials for biomarker tests; however, the degree to which these disparities may decrease is unknown.

CONTEXT

Biomarker testing exemplifies the shift towards "personalized medicine," which tailors individuals' prevention, diagnosis, and treatment according to their genetic profile.[2] The field of biomarker testing and related treatment decisions is also rapidly evolving. The best practices related to biomarker tests change as new biomarkers are continually being discovered, and treatments developed and approved by the U.S. Food and Drug Administration (FDA).

In general, biomarker tests can fall into two categories. *Prognostic* tests identify the patient's overall cancer outcome or likelihood of developing cancer. *Predictive* tests inform the effect of a therapeutic intervention in a patient and can be used to tailor treatment. Biomarker tests for patients with stage 3 or 4 cancer fall into this latter category. Predictive biomarkers[3] may change over time within a single tumor or may be different if cancer is a reoccurrence. Whether biomarkers change may also indicate whether treatments are nonresponsive.

Typically, single biomarker tests and liquid biopsies take between 7 and 10 days to be completed. Tissue next-generation sequencing (NGS) can take 3 to 4 weeks total: one week is usually required for the specimen to be prepared and sent out by the pathology lab to a

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

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

[3] Prognostic biomarkers do not change over time.

commercial vendor and the remaining time is used to run and interpret the assay.

There is consensus among clinical guidelines about the cancers for which predictive biomarker tests should be performed. Results from these tests are then used to inform cancer treatment recommendations. Performing biomarker testing enables a provider to accurately match the therapy to an individual patient by focusing on those most likely to be effective, and decreases treatment harms by avoiding treatments that are unlikely to result in improvement, do not target specific cancer cells (e.g., chemotherapy), or may result in an adverse reaction.

BILL SUMMARY

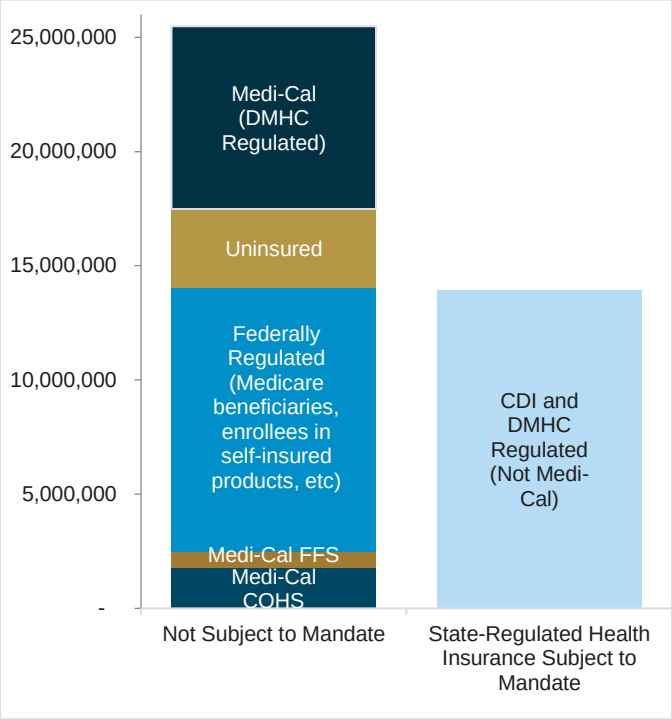
SB 535 would prohibit individual and group plans and policies from requiring prior authorization for biomarker testing for:

- Enrollees with advanced or metastatic stage 3 or 4 cancer; and
- Cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

The bill defines a biomarker test as “a diagnostic test of the cancer patient’s biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer, in order to guide patient treatment.”

Figure A notes how many Californians have health insurance that would be subject to SB 535.

Figure A. Health Insurance in CA and SB 535



Source: California Health Benefits Review Program, 2021.

PRIOR AUTHORIZATION

Prior authorization is a utilization management technique commonly used by health insurance carriers to ensure that a given medical intervention meets the insurance plan or policy’s criteria for coverage. The process typically requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment.

Plans and policies are required to provide an answer to a prior authorization request within five business days or within 72 hours if the enrollee faces a serious threat to their health.

The speed at which a provider submits the prior authorization request to the plan or insurer may vary. Larger health systems or offices may have more experience submitting prior authorization requests and are aware of the required information, while smaller offices or those with less experienced staff may not be as familiar and may take longer to submit the prior authorization request. Once the paperwork is submitted, a plan or policy can take up to five days to return a

decision[4]; then the biomarker test may take up to 4 weeks to complete. Some biomarker testing companies provide assistance with requesting prior authorization for the biomarker test from insurers. Once the patient and provider have the results of the biomarker test, they can make decisions about whether a molecular-targeted therapy is indicated for treatment. Administering this medication also usually involves a prior authorization request, with similar efforts on the part of the provider's office.

IMPACTS

Benefit Coverage, Utilization, and Cost

Due to data limitations described below, CHBRP has provided an upper bound of potential impacts due to SB 535. CHBRP makes the following assumptions and approach decisions:

- To determine the number of enrollees with stage 3 or 4 cancer, CHBRP used the Centers for Disease Control and Prevention (CDC) Wonder Data, adjusted by the National Institute's SEER data. This results in an assumption that approximately 46% of enrollees with cancer have stage 3 or 4 cancer.
- CHBRP assumes each enrollee with stage 3 or 4 cancer would have a biomarker test. However, because biomarker testing is not recommended for all cancers or enrollees with stage 3 or 4 cancer, this assumption results in an overestimate of utilization.

Benefit Coverage

At baseline, 100% of enrollees with health insurance that would be subject to SB 535 have benefit coverage for biomarker testing. Approximately 31% of enrollees have benefit coverage that requires prior authorization for biomarker testing. Of the 69% of enrollees with benefit coverage that does not require prior authorization at the plan level, prior authorization may be required at the provider level due to provider group policies (e.g., a medical group could require its providers to submit prior authorization requests to the medical group, instead of to the health plan). CHBRP is unable to quantify this percent.

Postmandate, 100% of enrollees would have coverage for biomarker testing without prior authorization. However, SB 535 would not require coverage of biomarker testing that is considered experimental or if a plan or policy determines biomarker testing is not medically necessary. It is possible an enrollee would be denied coverage for biomarker testing postmandate due to these reasons, although CHBRP is unable to estimate this frequency.

Utilization

At baseline, approximately 15,902 enrollees receive biomarker tests. Of these enrollees, approximately 4,851 enrollees have prior authorization requirements and 11,051 do not. The number of enrollees for whom authorization for biomarker testing is denied is 2,294. For enrollees denied approval for biomarker testing at baseline, CHBRP assumes 86.5% (1,985) would receive the biomarker test as a noncovered benefit and would pay the full cost ($3,642) out of pocket.

Postmandate, the 4,851 enrollees with prior authorization requirements and an additional 309 enrollees would receive biomarker testing that is not subject to prior authorization requirements.

CHBRP assumes, postmandate, all enrollees would receive the biomarker test without prior authorization as a covered benefit. It is possible some biomarker tests may be denied coverage postmandate and an enrollee would pay out of pocket for the service.

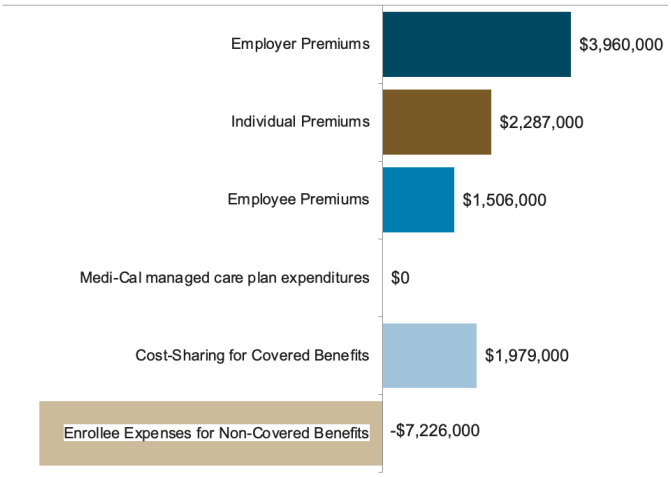
Expenditures

SB 535 would increase total net annual expenditures by $2,506,000 or 0.0019% for enrollees with DMHC-regulated plans and CDI-regulated policies (see Table 1). This is due to a $7,753,000 increase in total health insurance premiums paid by employers and enrollees for covered benefits and a $1,979,000 increase in enrollee cost sharing for covered benefits, adjusted by a $7,226,000 decrease in enrollee expenses for noncovered benefits.

CHBRP is unable to determine how or if treatments would change as a result of SB 535, and therefore what the impact would be on total expenditures. It is possible that administrative time spent by providers, medical offices, and health plans and policies would decrease, which could result in administrative cost savings.

[4] Should the initial prior authorization request be denied by a plan or policy, an enrollee or provider can appeal the decision, which adds to the amount of time required to obtain approval for the biomarker test.

Figure B. Expenditure Impacts of SB 535



Source: California Health Benefits Review Program, 2021.

Medi-Cal

Enrollees with coverage through Medi-Cal managed care plans do not have health insurance subject to SB 535. Therefore, there is no impact for these enrollees.

CalPERS

CalPERS HMOs would experience a total per member per month premium increase of $0.02.

Number of Uninsured in California

Because the change in average premiums would not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 535.

Medical Effectiveness

CHBRP did not identify any studies that examined the impact of prior authorization for biomarker testing on processes of care, such as timeliness of testing, probability of receipt of targeted therapy for those who would benefit from it, or timeliness of receipt of targeted therapy. However, there is *limited evidence*[5] that prior authorization for cancer treatment can delay initiation of treatment and lead some people to abandon treatment. There is also *limited evidence* that delays in obtaining results of biomarker tests could reduce use of first-line targeted therapies and consequently negatively affect health outcomes. While there is *insufficient evidence*[6] specifically regarding delays caused by prior authorization for biomarker testing, it is possible that prior authorization could exacerbate delays in obtaining results of biomarker tests.

There is *insufficient evidence* that prior authorization for biomarker testing impacts cancer outcomes for individuals with metastatic or advanced stage 3 or 4 cancer. No studies were identified that examined the impact of prior authorization for biomarker testing on remission rates, incidence of death, or survival rates. There is *limited evidence* that delays in receipt of systemic therapy, such as targeted therapy, impacts mortality risk for cancer; effects may vary by cancer type. To the extent that prior authorization delays biomarker testing, it could delay initiation of targeted therapies, which could increase mortality among persons with cancers for which targeted therapies are available and effective.

Public Health

Cancer care is complex and there are many factors that impact testing and treatment decisions. While the removal of prior authorization has the potential to decrease time to treatment, there is no evidence that evaluates this directly. Because there is insufficient evidence of the impact of prior authorization on biomarker testing, the public health impact of SB 535 is unknown. Please note that the absence of evidence is not “evidence of no effect.” It is possible that an impact — desirable or undesirable — could result, but current evidence is insufficient to inform an estimate.

However, there is some evidence that delays in testing results impact treatments delivered for cancer, and that delays in treatment may lead to poorer health outcomes. Should SB 535 result in fewer delays in obtaining biomarker test results, there is the potential for a limited public health impact.

CHBRP also found evidence of disparities in rates of biomarker testing by income, with people of lower socio-economic levels receiving biomarker testing at lower rates. SB 535 could result in a reduction of income and racial/ethnic disparities in biomarker testing rates due to a decrease in coverage denials for biomarker tests; however, the degree to which these disparities may decrease is unknown.

[5] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.
[6] *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.

Long-Term Impacts

The impacts of SB 535 are unlikely to be different in subsequent years, assuming the same number of biomarker tests and targeted therapies are available. However, changes in clinical recommendations regarding biomarker testing and the availability and number of biomarker tests may lead to increased utilization of biomarker testing, which would impact overall expenditures. There are anticipated changes in biomarker testing recommendations and targeted treatments for cancers, pending FDA approval.

Essential Health Benefits and the Affordable Care Act

SB 535 would not require coverage for a new state benefit mandate 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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Table 1. SB 535 Impacts on Benefit Coverage, Utilization, and Cost, 2022

	Baseline (2022)	Postmandate Year 1 (2022)	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,945,000	21,945,000	0	0.00%
Total enrollees with health insurance subject to SB 535	13,940,000	13,940,000	0	0.00%
Total percentage of enrollees with health insurance subject to SB 535	64%	64%	0%	0.00%
Total percentage of enrollees with health insurance subject to SB 535 with compliant coverage	69%	100%	31%	45.29%
Utilization and Cost				
Estimated number of users of biomarker tests				
With prior-authorization (includes approved and denied tests)	4,851	0	(4,851)	-100%
Without prior-authorization	11,051	16,211	5,160	46.70%
Of users denied biomarker tests, estimated number of users who got the test as a noncovered benefit				
Number of tests denied during the prior-authorization request	1,985	0	(1,985)	-100%
Average per user cost of biomarker panel tests				
Biomarker panel test cost	$3,642	$3,642	$0	0.00%
Average cost sharing for biomarker panel tests				
With prior-authorization	$835	$0	-$835	-100%
Without prior-authorization	$612	$687	$75	12.23%
Expenditures				
Premium (expenditures) by Payer				
Private employers for group insurance	$55,032,803,000	$55,036,629,000	$3,826,000	0.0070%
CalPERS HMO employer expenditures (b) (c)	$5,765,017,000	$5,765,151,000	$134,000	0.0023%
Medi-Cal managed care plan expenditures	$24,150,529,000	$24,150,529,000	$0	0.0000%
Enrollee premiums (expenditures)				
Enrollees for individually purchased insurance	$15,847,507,000	$15,849,794,000	$2,287,000	0.0144%
Individually purchased – outside exchange	$4,890,852,000	$4,891,622,000	$770,000	0.0157%
Individually purchased – Covered California	$10,956,655,000	$10,958,172,000	$1,517,000	0.0138%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$20,753,446,000	$20,754,952,000	$1,506,000	0.0073%
Enrollee out-of-pocket expenses				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	$13,168,032,000	$13,170,011,000	$1,979,000	0.0150%
Expenses for noncovered benefits (d)	$7,226,000	$0	-$7,226,000	-100%
Total Expenditures	$134,724,560,000	$134,727,066,000	$2,506,000	0.0019%

Source: California Health Benefits Review Program, 2021.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(b) Of the increase in CalPERS employer expenditures, about 54.1% or $72,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

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

(e) Since these biomarker tests are not covered by a plan or policy, the enrollee pays the full amount out of pocket.

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

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[7] conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 535, Biomarker Testing.

Bill-Specific Analysis of SB 535, Biomarker Testing

Bill Language

SB 535 would prohibit individual and group plans and policies from requiring prior authorization for biomarker testing for:

- Enrollees with advanced or metastatic stage 3 or 4 cancer; and
- Cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

The bill defines a biomarker test as "a diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer, in order to guide patient treatment."

The full text of SB 535 can be found in Appendix A.

Relevant Populations

If enacted, SB 535 would apply to the health insurance of approximately 13.9 million enrollees (35% of all Californians). This represents 64% of the 21.9 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, exempting Medi-Cal managed care plans.

Because SB 535 specifies "group and individual" plans and policies, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to SB 535's requirements.[8]

Analytic Approach and Key Assumptions

CHBRP previously provided a background brief based on similar bill language, AB 2640 in 2020. Where applicable, this analysis builds off of that previous brief.

CHBRP interprets the bill language as only prohibiting prior authorization for *covered* biomarker testing. Plans and policies would still be permitted to deny coverage of biomarker testing postmandate according to their coverage determination policies.

CHBRP focuses this analysis on biomarkers for which there are tests that can inform treatment (predictive biomarkers). This analysis does not focus on prognostic biomarkers. More information is provided in the *Background* section.

[7] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[8] Personal communication, W. White, California Department of Health Care Services, March 2020.

Interaction With Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

CHBRP is not aware of any California law or regulations related to genetic biomarker testing. CHBRP is aware of requirements for state-regulated health insurance plans and policies to cover "all generally medically accepted cancer screening tests." Screening tests are administered to asymptomatic people to detect cancerous or precancerous lesions so that they can be treated early, which can reduce the risk that a person will develop metastatic or advanced cancer. Thus, this mandate is unrelated to tumor biomarker testing for enrollees with metastatic or advanced stage 3 or 4 cancer.

Under California law, if prior authorization is required for nonemergency medical services for enrollees in DMHC-regulated plans or CDI-regulated policies, prior authorization must be given immediately, but no more than five calendar days after the request for preauthorization.[9] When an enrollee's condition is such that they face an imminent and serious threat to their health, an insurer must make a prior authorization determination within 72 hours of a request.[10]

Similar requirements in other states

At least two states (Illinois[11] and Massachusetts[12]) have introduced legislation near identical to SB 535 in 2021.

Louisiana's governor signed SB 204 into law in 2020. This law would prohibit a plan from denying coverage for treatment of metastatic or unresectable tumors with a medication on the sole basis that the drug is not indicated for the location in the body of the patient's cancer if the drug is approved by the U.S. Food and Drug Administration (FDA) for treatment of the specific mutation of a patient's cancer.

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 535 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[13,14]

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.

[9] H&SC 1367.01(h)(1); California Insurance Code 2695.11.
[10] H&SC 1367.01(h)(2); California Insurance Code 10123.135(h)(2).
[11] House Bill 1779.
[12] SD 1084.
[13] 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. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[14] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets 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.[15,16] CHBRP estimates that approximately 4.2 million Californians (11%) have insurance coverage subject to EHBs in 2022.[17]

States may require plans and policies to offer benefits that exceed EHBs.[18] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.[19,20] Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.[21]

SB 535 would not require coverage for a new state benefit mandate and therefore appears not to exceed the definition of EHBs in California.

[15] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[16] H&SC Section 1367.005; IC Section 10112.27.
[17] CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.
[18] ACA Section 1311(d)(3).
[19] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[20] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[21] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

BACKGROUND ON BIOMARKER TESTING

As described in the *Policy Context* section, SB 535 prohibits commercial and CalPERS plans and policies from requiring prior authorization for biomarker testing for enrollees with advanced or metastatic stage 3 or 4 cancer. This section includes an overview of biomarker testing, cancers for which biomarker testing is used, and how prior authorization may impact treatment.

Cancer Prevalence in California

In 2021, it is estimated 187,140 Californians will be newly diagnosed with cancer, a set of diseases characterized by abnormal cell growth (ACS, 2020). The rate of cancer cases per 100,000 females has decreased over the past 30 years. In 2016, the rate of cancer diagnosis was 381 cases per 100,000 females, down from about 451 in 1988 when statewide cancer reporting began (Movsisyan et al., 2019). Among males in California, the age-adjusted cancer incidence rate decreased by almost 23% between 1988 and 2016.

The 10 most common types of cancer among California males and females accounted for 77.8% of all new diagnoses, and 74.4% of all cancer-related deaths (Movsisyan et al., 2019). The most common types of cancer among California males and females is described in Table 2 below.

Additionally, there are existing disparities in incidence and screening for cancer by race and ethnicity and income (Movsisyan et al., 2019; Zavala et al., 2021). Incidence of breast cancer is highest among non-Hispanic White women, followed by Black women, Asian and Pacific Islander women, Hispanic women, and American Indian or Alaska Native women. However, Black women and Asian and Pacific Islander women have a higher risk of breast cancer–specific mortality relative to non-Hispanic White women. Prostate cancer disparities constitute the largest of all cancer disparities: the incidence among Black men is 78% higher than among non-Hispanic White men. Black men are also more likely to be diagnosed at a younger age, present with more advanced and aggressive disease, and have a 2.3-times higher mortality rate compared with non-Hispanic White men. For lung cancer, Black men have the highest incidence rate compared to other racial and ethnic groups.

Table 2. Ten Most Common Types of Cancer Among California Males and Females, 2016

Females	Males
Breast	Prostate
Lung and bronchus	Lung and bronchus
Colon and rectum	Colon and rectum
Corpus and uterus NOS	Melanoma of the skin
Thyroid	Urinary bladder
Melanoma of the skin	Non-Hodgkin lymphoma
Non-Hodgkin lymphoma	Kidney and renal pelvis
Ovary	Oral cavity and pharynx
Pancreas	Leukemia
Kidney and renal pelvis	Liver and intrahepatic bile duct

Source: California Health Benefits Review Program, 2020. Adapted from Movsisyan et al., 2019.

Metastatic and Advanced Stage 3 or 4 Cancer

The assignment of cancer "stages," or "staging," is a process by which medical providers determine the extent of cancer growth in the body (NCCN, 2020). Most often, physicians use the TNM staging system developed and maintained by the American Joint Committee on Cancer and Union for International Cancer Control. The letters describe different aspects of cancer growth. The TNM system is used for the majority of cancers, but not for all of them; one common exception to the TNM staging system is lymphoma (NCCN, 2020).

In the TNM staging system, the "T" denotes the extent of the primary tumor, or first mass of cancer cells in the body. The N refers to lymph nodes and denotes the extent of cancer in those nodes that are close to the origin of the cancer. "M" refers to "metastasis," or spread to distant sites in the body. TNM values, if used, are then combined to assign an overall stage to the cancer (ACS, 2015). Stage groups are determined based on where the cancer has grown and spread, and patients in the same stage group tend to have similar prognoses (NCCN, 2020).

Stage 3 cancer generally denotes that the cancer is larger than lower stages (stages 0–2) and has possibly spread to surrounding tissues and/or lymph nodes. Stage 4 cancer denotes that cancer has spread from its origin to at least one other organ (also known as "secondary" or "metastatic" cancer) (NHS, 2018).

The overall prevalence of metastatic or stage 3 or 4 cancer is unknown.

Biomarker Testing

Biomarker testing exemplifies the shift towards "personalized medicine," which tailors individuals' prevention, diagnosis, and treatment according to their genetic profile (NIH, 2020). The field of biomarker testing and related treatment decisions is also rapidly evolving. The best practices related to biomarker tests change as new biomarkers are continually being discovered, and treatments developed and FDA approved.

Types of Biomarker Tests

In general, biomarker tests can fall into two categories (Oldenhuis, 2008). *Prognostic* tests identify the patient's overall cancer outcome or likelihood of developing cancer. *Predictive* tests inform the effect of a therapeutic intervention in a patient and can be used to tailor treatment. Biomarker tests for patients with stage 3 or 4 cancer fall into this latter category.

Biomarker tests may be performed using several assays, or clinical tests (ONS, 2021):

- Fluorescence in situ hybridization (FISH) is a technique for detecting and locating a specific DNA sequence on a chromosome.
- Immunohistochemistry (IHC) uses antibodies to check for certain antigens in tissue samples and is used to help diagnose diseases or differentiate between types of cancers.
- Next-generation sequencing (NGS) is a high-throughput method that uses DNA sequencing technology to determine a portion of the nucleotide sequence of an individual's genome.
    - NGS can be tested in tissue and in blood typically known as a liquid biopsy using circulating tumor DNA (ctDNA). A liquid biopsy may be used to help plan treatment especially if there is insufficient tissue to perform NGS and/or to monitor out how well treatment is working. For patients that progress on current treatment, it may provide the mechanism of resistance and avoid another biopsy that can result in additional precision therapy options.
- Sanger sequencing uses polymerase chain reaction (PCR) and is a low-throughput method to determine a portion of the nucleotide sequence of an individual's genome.

NGS and liquid biopsy are the most frequently used testing methods for biomarkers relevant to metastatic cancers and their utilization will continue to grow. The primary advantage of NGS is its ability to test multiple biomarkers simultaneously (El-Deiry et al., 2019). However, single gene tests may be appropriate in selected circumstances.

Predictive biomarkers[22] may change over time within a single tumor or may be different if cancer is a reoccurrence. Whether biomarkers change may also indicate whether treatments are nonresponsive.

Typically, single biomarker tests and liquid biopsies take between 7 and 10 days to be completed. Tissue NGS can take 3 to 4 weeks total: one week is usually required for the specimen to be prepared and sent out by the pathology lab to a commercial vendor and the remaining time is used to run and interpret the assay.

Clinical Guidelines for Biomarker Testing

There is consensus among clinical guidelines about the cancers for which predictive biomarker tests should be performed. Results from these tests are then used to inform cancer treatment recommendations.

Performing biomarker testing enables a provider to accurately match the therapy to an individual patient by focusing on those most likely to be effective, and decreases treatment harms by avoiding treatments that are unlikely to result in improvement, do not target specific cancer cells (e.g., chemotherapy), or may result in an adverse reaction (NASEM, 2016).

Table 3 below provides an overview of the available predictive biomarker tests, cancers for which they are relevant and recommended, and indicated treatments. The science surrounding biomarker testing and related treatments is evolving; even though biomarker testing may help identify mutations, there may not be treatments to target the mutation. Additionally, the FDA has approved biomarker tests and related molecularly targeted treatments for specific types of tumors. Some patients and physicians may explore off-label use of approved medications in order to treat other types of tumors. CHBRP does not include further discussion of this use.

Table 3. Clinically Recommended Biomarker Tests for Advanced/Metastatic or Stage 3/4 Cancers

Biomarker	Condition(s)	Treatment Drug(s)	References
ALK	Non-small cell lung cancer, thyroid cancer	Alectinib, brigatinib, ceritinib, crizotinib, lorlatinib	NCCN, 2021e, 2021g
BRAF	Colorectal cancer, non-small cell lung cancer, cutaneous melanoma, thyroid cancer	Dabrafenib, encorafenib, trametinib, vemurafenib	ASCO, 2018; Dummer, 2015, 2019; NCCN, 2021e, 2021g; NICE, 2020
BRCA1/2	Breast cancer, prostate cancer	Olaparib, rucaparib, talazoparib	Giri et al., 2020; NCCN, 2021a, 2021f
EGFR	Non-small cell lung cancer	Afatinib, dacomitinib, erlotinib (in combination with ramcuriumab or bevacizumab), gefitinib, osimertinib	NCCN, 2021e; NICE, 2013

[22] Prognostic biomarkers do not change over time.

HER2	Breast cancer, gastric cancer, gastroesophageal adenocarcinoma, non-small smell lung cancer	Ado-trastuzumab emtansine, lapatinib, fam-trastuzumab deruxtecan-nxki, fluoropyrimidine and trastuzumab (in combination with oxaliplatin or cisplatin), trastuzumab, pertuzumab	ASCO, 2013, 2017a; Bartley et al., 2016; NCCN, 2021c
KIT	Cutaneous melanoma	Imatinib, nilotinib	Michielin, 2019; NCCN, 2021d
KRAS	Colorectal cancer	Cetuximab, panitumumab	ASCO, 2017b; NICE, 2020
MET	Non-small cell lung cancer	Capmatinib, crizotinib, tepotinib	NCCN, 2021e
NTRK 1/2/3	Breast cancer, endometrial carcinoma, gastroesophageal adenocarcinoma, non-small cell lung cancer, thyroid cancer, uterine sarcoma, vulvar cancer	Entrectinib, larotrectinib	NCCN, 2020, 2021a, 2021b, 2021c, 2021e, 2021g
RET	Non-small cell lung cancer, thyroid cancer	Cabozantinib, pralsetinib, selpercatinib, vandetanib	NCCN, 2021e, 2021g
ROS1	Non-small cell lung cancer	Ceritinib, crizotinib, entrectnib, lorlatinib	NCCN, 2018, 2019, 2021e; Sequist & Neal, 2020

Source: California Health Benefits Review Program, 2021.
Note: Table does not include hematologic cancers.

Table 4. Recommendations and Guidelines for Multigene Testing in Advanced or Metastatic Cancers

Number of Genes	Criteria	References
Testing of 5 to 50 genes	Genes must be clinically relevant and cited in the label of an FDA-approved companion diagnostic; he test should not be more expensive than the cost of individual testing	CMTP, 2015
Testing of 50 or more genes	Stage IV non-small cell lung cancer, rare or stage IV solid tumors (e.g., lung and pancreatic cancers), cancers that are unresponsive to treatment or exhausted other treatment options	CMTP, 2015
Number of genes unspecified	Genetically heterogeneous disorders and oncology applications, circumstances requiring evaluation of multiple high-penetrance genes of established clinical utility or association with cancer risks and mutations, or identifying rare driver mutations for which effective drugs may be available	ACMG, 2013; ASCO, 2015; CMTP, 2015; NCCN, 2017

Source: California Health Benefits Review Program, 2021.

Cancer Treatment

Time to Treatment Initiation for Cancer

Delays in time to treatment initiation for new cancer diagnoses are commonly known to cause patient anxiety and distress (Khorana et al., 2019). Evidence is mixed depending on the stage and type of cancer whether increased time to treatment is associated with poorer outcomes (Khorana et al., 2019). A recent

study investigated trends in time to treatment initiation and the relationship to overall survival for newly diagnosed, early-stage solid tumors. Khorana et al. (2019) found the median time to treatment was 27 days and increased significantly between 2004 and 2013 for most cancers. The authors found predictors of increased time to treatment initiation included receiving care at an academic medical center, Black race, lower levels of education, lack of a prior history of cancer, transferring care to another facility or provider, and being uninsured. For the majority of cancers included in the study, increased time to treatment initiation was associated with worsened survival. The largest association was seen in pancreas and non-small cell lung cancer (NSCLC). Every week of increased time to treatment initiation was associated with increased risk of death by an estimated 3% in stage 1 and 2.4% in stage 2 for pancreas cancer and 3.2% in stage 1 and 1.6% in stage 2 for NSCLC. These results may or may not be generalizable to patients with stage 3 or 4 cancer.

A recent systematic review examined the relationship between cancer treatment delay and mortality from seven major cancer types (bladder, breast, colon, rectum, lung, cervix, and head and neck cancer) across three treatment modalities: surgery, radiotherapy, and systemic therapy (which includes targeted therapy) (Hanna et al., 2020). The authors broadly concluded that a four-week treatment delay is associated with an increase in mortality risk across all three treatment modalities, although effects varied for cancers for which targeted therapies exist (cancers for which there are FDA-approved targeted therapies are included in Table 3). The authors found significant associations between delays in adjuvant and neoadjuvant systemic therapy and mortality risk for breast, colon, and rectal cancer; they did not find significant associations for non-small cell lung cancer.

Precision Oncology

As mentioned above, biomarker testing is used to inform which treatments may be the most effective. For patients who receive biomarker testing and receive appropriate targeted therapy, studies have found median overall survival about twice as great than for patients who received standard chemotherapy or best supportive care (51.7 weeks vs 25.8 weeks, respectively) (Haslem et al., 2017). Additionally, the average per-week cost of treatment was lower for patients who received targeted therapy ($2,720 vs $3,453 for the control group). Patients receiving targeted therapy had higher drug and sequencing charges, but these were offset by lower inpatient and outpatient charges. The relative resource use for these patients was approximately 40% lower across all sites of care (inpatient, outpatient, and emergency department). Sadaps et al. (2018)[23] also found increased survival rates for patients receiving targeted therapy (18 months vs 14 months for patients that received other therapies).

A more recent analysis of biomarker testing rates, targeted therapy use, and mortality outcomes using data from a large U.S. health care delivery system found that a large majority of patients with NSCLC (83.9%) received at least one biomarker test (John et al., 2020).[24] Rates of testing were higher in later years of the study period (62.2% between 2014 and 2018 vs 21.7% between 2011 and 2013). Similar trends were found in the studies by Haslem et al. (2017) and Sadaps et al. (2018). Overall, 30% of patients in John et al.'s (2020) study had a positive test result for at least one biomarker and more than half of patients who had biomarker testing received a biomarker-driven therapy (52.8%). Biomarker testing and targeted therapy as the first line of treatment were associated with greater survival compared to those who did not receive biomarker testing (median survival of 18 months vs 6 months).

Prior Authorization

Prior authorization — also known as preauthorization, precertification, prior approval, or prospective review — is a utilization management technique commonly used by health insurance carriers to ensure that a given medical intervention meets the insurance plan or policy's criteria for coverage (Newcomer et

[23] Authors of this study received funding from pharmaceutical and biotech companies; the study also received support from a biomarker testing company.
[24] This study was sponsored by Roche and the authors are employees of various biotech companies, including Roche and Genentech.

al., 2017). Prior authorization developed as a tool for insurers to assess the appropriateness of treatment that would result in a hospital admission or a high-cost procedure (Resneck, 2020). The process typically requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment.

As mentioned in the *Policy Context* section, plans and policies are required to provide an answer to a prior authorization request within five business days or within 72 hours if the enrollee faces a serious threat to their health.

The speed at which a provider submits the prior authorization request to the plan or insurer may vary. Larger health systems or offices may have more experience submitting prior authorization requests and are aware of the required information, while smaller offices or those with less experienced staff may not be as familiar and may take longer to submit the prior authorization request. Once the paperwork is submitted, a plan or policy can take up to five days to return a decision[25]; then the biomarker test may take up to 4 weeks to complete. Some biomarker testing companies provide assistance with requesting prior authorization for the biomarker test from insurers.[26] Once the patient and provider have the results of the biomarker test, they can make decisions about whether a molecular-targeted therapy is indicated for treatment. Administering this medication also usually involves a prior authorization request, with similar efforts on the part of the provider's office.

A 2017 ASCO survey of oncology practices found that prior authorization (78%) and coverage denials/appeals (62%) were the most frequently cited challenges (Kirkwood et al., 2018). The responses were similar across practice settings (academic, hospital/health system–owned, and physician-owned) for prior authorization, but responses for coverage denials/appeals were more varied. Although not specific to oncologists, a 2017 American Medical Association survey of found that more than 90% of physicians surveyed reported delays in care as a result of prior authorization, 78% of physicians reported that prior authorization led to treatment plan abandonment at least some of the time, and 61% reported significant effect on patients (AMA, 2018).

Disparities[27] and Social Determinants of Health[28] in Biomarker Testing

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to prevalence of cancers for which biomarker testing may be recommended. Disparities are noticeable and preventable differences between groups of people.

CHBRP found literature identifying disparities in genetic testing by race and ethnicity and income.

Race and Ethnicity[29]

Lynch et al. (2018) found discrepancies in testing for mutations in the epidermal growth factor receptor (EGFR) gene, the testing of which is indicated for all newly diagnosed patients with metastatic lung

[25] Should the initial prior authorization request be denied by a plan or policy, an enrollee or provider can appeal the decision, which adds to the amount of time required to obtain approval for the biomarker test.
[26] Personal communication with Karen Kelly, MD, on March 10, 2021.
[27] 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).
[28] 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: (CDC, 2014; Healthy People 2020, 2019). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.
[29] CHBRP identified several studies that found that Black women are less likely to be tested for the BRCA1 and BRCA2 gene mutations, but because those mutations are identified to determine the likelihood that a person may

cancer. Hispanic and Black people were less likely to be tested than White people and Asian/Pacific Islanders. This happened even as overall testing rates increased from 2011 to 2013 (by 19.7%).

Income

Lynch et al. (2018) also found disparities in testing for EGFR gene by socioeconomic status. Medicare enrollees who were dually enrolled in Medicaid were 16% less likely to receive a biomarker test compared to Medicare-only enrollees (odds ratio [OR] 0.74; 95% confidence interval [CI], 0.72–0.77).

A recent systematic review and meta-analysis found low socio-economic status was associated with modestly lower predictive biomarker test utilization and significantly lower biological and precision therapy utilization (Norris et al., 2020). Patterns of lower utilization by socio-economic status were consistent (OR 0.86; 95% CI, 0.71–1.05) across cancers included in the studies (breast cancer, colorectal cancer, melanoma, and non-small cell lung cancer), although only statistically significant for colorectal cancer. The overall pooled OR for receipt of biological and precision therapy for patients from low socio-economic status was 0.83 (95% CI, 0.75–0.91). Associations with therapy utilization were strongest in lung cancer (OR 0.75, 95% CI, 0.51–1.00) and weakest in breast cancer (OR 0.93; 95% CI, 0.78–1.10).

Similar socio-economic disparities have been observed across the cancer care pathways, from screening, to diagnosis, and timeliness of referral and treatment receipt, through to survival (Norris et al., 2020). The authors note that it is not clear why the strength of socio-economic disparities varied by cancer type. The risk of developing some cancers is associated with health behaviors (e.g., smoking) and it is possible that these behaviors, alongside other factors, such as multi-morbidity, could influence a health care professional's decision to offer or initiate, or a patient's choice to receive, cancer treatment.

develop cancer, and not to treat cancer once it's already been identified, those studies have been excluded from discussion.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 535 would prohibit prior authorization for biomarker testing for enrollees with stage 3 or 4 advanced or metastatic cancer. Additional information on cancer prevalence in California, biomarker testing, and prior authorization is included in the *Background* section. CHBRP was unable to identify studies that specifically examine the impact of prior authorization for genetic biomarker testing. The medical effectiveness review summarizes findings from evidence[30] on prior authorization for cancer treatment. Therefore, caution should be exercised when interpreting the findings of the studies CHBRP reviewed because their generalizability to prior authorization for genetic biomarker testing is unknown.

Research Approach and Methods

CHBRP had previously conducted thorough literature searches on prior authorization for biomarker testing for stage 3 or 4 advanced or metastatic cancer in 2020 for AB 2640. That search did not return any literature specifically on prior authorization for genetic biomarker testing for advanced, metastatic, or stage 3 and 4 cancer. A new literature search was conducted for SB 535.

Studies of genetic biomarker testing for advanced, metastatic, or stage 3 or 4 cancer were identified through searches of PubMed, EMBASE, Web of Science, Cochrane Library from 2020 to the present, and website of the National Comprehensive Cancer Network.

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

The search excluded studies of genetic biomarker testing for conditions other than cancer. Because SB 535 addresses the issue of prior authorization for genetic biomarker testing for cancer, *not* coverage for cancer treatment, we excluded studies on the effectiveness of cancer treatments and biomarker testing and instead focused on identifying studies of the impact of prior authorization on access to biomarker testing, timeliness of testing and treatment, and health outcomes.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[31] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. Does prior authorization for genetic biomarker testing reduce access to these tests among individuals who have advanced or metastatic stage 3 or 4 cancer?

2. Does prior authorization for genetic biomarker testing delay testing among individuals who have advanced or metastatic stage 3 or 4 cancer?

3. Does prior authorization for genetic biomarker testing reduce the probability that people with advanced or metastatic stage 3 or 4 cancer who would benefit from targeted therapy will receive it?

[30] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

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

4. Does prior authorization for genetic biomarker testing affect the timeliness of receipt of targeted therapy among individuals who have advanced or metastatic stage 3 or 4 cancer?

5. Does prior authorization for genetic biomarker testing affect cancer outcomes among individuals who have advanced or metastatic stage 3 or 4 cancer?

Methodological Considerations

CHBRP conducted the literature search with the objective of understanding how prior authorization for genetic biomarker testing for advanced, metastatic, or stage 3 or 4 cancer affects the following health outcomes:

- Access to genetic biomarker testing
- Timeliness of genetic biomarker testing
- Initiation of targeted therapy
- Timeliness of initiation of targeted therapy
- Incidence of remission
- Incidence of death
- Survival rate

However, CHBRP was unable to identify studies that specifically examine the impact of prior authorization for genetic biomarker testing for cancer at any stage on any of the outcomes listed above. The only studies identified examined the impact of prior authorization on processes of care for cancer treatment. Therefore, caution should be exercised when interpreting the generalizability of cited studies' findings to genetic biomarker testing for advanced, metastatic, or stage 3 or 4 cancer. No studies that included incidence of remission, incidence of death, and survival rate as outcomes were identified.

Outcomes Assessed

The outcomes assessed by studies included in this review include access to cancer treatment (medication and therapy) and timeliness of cancer treatment.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of prior authorization for genetic biomarker testing for advanced, metastatic, or stage 3 or 4 cancer. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

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

Clear and convincing evidence indicates that there are multiple studies of a treatment[32] and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

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

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

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

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

More information is available in Appendix B.

Processes of Care

CHBRP did not identify any studies on the impact of prior authorization for genetic biomarker testing on processes of care, such as timeliness of testing and timeliness of receipt of treatment for cancer at any stage. Five studies were identified that examined the prior authorization approval process for *cancer medications* and *proton beam therapy treatments.* Given that these five studies are about prior authorization requirements for medications and treatments, the results may not be fully generalizable to prior authorization for genetic biomarker testing. However, they may offer insights into the extent to which prior authorization requirements are associated with delays testing or receipt of treatment that could negatively affect health outcomes.

Prior authorization approval process

Cancer medications

The first study examined the impact of prior authorization for breast cancer medications on the process of care at a breast cancer oncology clinic (Agarwal et al., 2017). The researchers tracked prior authorization approval rates and time to approval for various specialty breast cancer medications. They found that most prior authorizations (97.5%) were approved on the first prior authorization request after an average time of 0.82 days (range = 0 to 14 days). The most common medication type requiring prior authorization was targeted therapy, which made up 28.1% of the prior authorizations examined. However, the researchers found that differences in drug indication (i.e., reason for prescribing the drug) did not have a statistically significant impact on approval time. Additionally, the researchers noted that while their study took place at a clinic in an academic center with a more centralized prior authorization process, the prior authorization process is often more convoluted in most practices, which is likely to result in further delays.

The second study examined the impact of frequency of prior authorization requests on the approval process for pediatric hematologic and oncologic medications (Dickens and Pollock, 2017). Researchers analyzed data from prior authorization requests at a pediatric hematology and oncology and bone marrow transplant clinic. Most requests were ultimately approved (98.5%) and the prescriptions were changed for

[32] In the case of SB 535, biomarker testing is the “treatment” for which CHBRP assessed the evidence.

the remaining 1.5%. Most requests were approved after the first attempt (80.3%). The remaining requests went through an appeals process, and reasons for initial denial included erroneous generation of the original medication prior authorization request (11.7%) and more documentation being required for approval (6.6%). Moreover, the researchers also found that prior authorization policies vary greatly across different payers. Ultimately, the researchers concluded that prior authorization for pediatric hematology and oncology medications led to no changes in care.

Proton beam therapy

Proton beam therapy (PBT) is a type of external radiation therapy that is used to treat various types of cancer. It is a local treatment and targets a specific part of the body. The rationale for PBT is that because proton beams do not scatter radiation on their path through the body and stop once reaching the tumor, PBT may reduce the amount of normal tissue exposed to radiation compared to conventional radiotherapy (NCI, 2018). This may lead to reduced toxicity, reduced likelihood for adverse events, and improvements in quality of life for cancer patients (Baumann et al., 2020; Verma et al., 2017). CHBRP identified three studies of prior authorization for PBT in its medical effectiveness literature search. Given that PBT, like the targeted medications for which genetic biomarker testing is undertaken, is a relatively new approach to treating cancer, CHBRP decided to include these articles in the literature review. However, caution should be exercised in interpreting the generalizability and applicability of findings from studies of prior authorization for PBT to prior authorization for biomarker testing.

The first study of the impact of prior authorization for PBT for cancer examined both adult and pediatric cancer patients (Gupta et al., 2019). The researchers found that while 9% of pediatric requests for PBT were initially denied and all were approved after repeal, 64% of adult requests were initially denied and 32% remained denied after repeal. Across a 3-year period, initial denial rates increased from 55% to 74%. Furthermore, the researchers found that prior authorization delayed treatment start by an average of 3 weeks (and up to 4 months) for those who required appeal after initial denial, resulting in 19% of denied patients abandoning radiation treatment altogether.

The second study examined patients with thoracic, head, or neck cancer who were considered for PBT, and compared those enrolled in Medicare with those enrolled in private insurance (Ning et al., 2019). The researchers found that Medicare enrollment was the strongest predictor of initial approval; 91% of Medicare enrollees were approved at initial request (with a median waiting period of 3 days), compared to 30% of private insurance enrollees (with a median waiting period of 14 days). Across both groups, the majority who were initially denied coverage appealed the decision (n=276, 90.2%); 68.5% of them subsequently had the denials overturned (with a median time of 21 days from initial inquiry).

The third study examined cancer patients at an academic medical center who were considered for PBT (Ojerholm and Hill-Kayser, 2018). Specifically, the study population included patients aged 18 years and under or patients aged 19 to 30 years with a pediatric primary tumor. Most initial requests were approved (89%). All but one of the initially denied requests were overturned upon appeal. The researchers also found that the odds of initial denial were 4.5 times higher for a non-central nervous system (CNS) malignancy compared to a CNS malignancy, and 3.9 times higher for patients older than 18 compared to patients aged 18 and under. They noted that this may suggest that payer practices with approving initial requests reflect general adherence to current evidence-based guidelines regarding PBT and pediatric and CNS malignancies.

Receipt of cancer treatment

CHBRP also did not identify any literature related to delayed cancer treatment as a result of prior authorization for biomarker testing. Lack of evidence is not evidence of a lack of effect. Instead, it indicates that the effect of prior authorization for biomarker testing on timeliness of cancer treatment is unknown. If prior authorization were to delay testing, it might lead to delays in obtaining test results, which could delay treatment.

CHBRP identified two studies examining the relationship between wait times for biomarker test results and treatment decisions and initiation. The first study examined a random sample of 300 patients with non-small cell lung cancer at a Canadian cancer treatment center who received biomarker testing (Lim et al., 2015). The researchers found that delays in obtaining test results delayed treatment decisions and initiation for patients with advanced non-small cell lung cancer. For example, only 21% of patients who received biomarker testing had results available at their initial oncology consultation. Of those with positive EGFR or ALK results, 19% started chemotherapy before their test results were available; the researchers noted that this could represent missed opportunities to instead initiate first-line targeted therapies. The second study utilized electronic health record data to examine ROS1 testing rates for 11,409 patients with non-small cell lung cancer (Wong et al., 2020). The researchers found that patients with delayed test results were nearly 10 times more likely to initiate treatment before test results and noted that timely ROS1 test results could inform provider decisions to initiate first-line targeted therapies rather than potentially unnecessary chemotherapy.

Summary of findings regarding the impact of prior authorization on process of care: No studies were identified that examined the impact of prior authorization for biomarker testing on processes of care, such as timeliness of testing, probability of receipt of targeted therapy for those who would benefit from it, or timeliness of receipt of targeted therapy. However, there is *limited evidence* that prior authorization for cancer treatment can delay initiation of treatment and lead some people to abandon treatment. There is also *limited evidence* that delays in obtaining results of biomarker tests could reduce use of first-line targeted therapies and, consequently, negatively affect health outcomes. While there is *insufficient evidence* specifically regarding delays caused by prior authorization for biomarker testing, it is possible that prior authorization could exacerbate the delays to obtaining results of biomarker tests.

Figure 1. Impact of Prior Authorization for Biomarker Testing on Initiation of Treatment

Figure 2. Impact of Prior Authorization for Biomarker Testing on Use of First-Line Targeted Therapies for Cancer

Health Outcomes

CHBRP did not identify any studies of the impact of prior authorization for biomarker testing on the health outcomes of people with cancer at any stage. Lack of evidence is not evidence of a lack of effect. Instead, it indicates that the effect of prior authorization on health outcomes is unknown. If prior authorization for biomarker testing were to delay receipt of targeted therapy, it could lead to worse health outcomes.

As described in the *Background* section, CHBRP identified one systematic review that examined the relationship between cancer treatment delay and mortality for seven major cancer types across three treatment modalities, although this study did not identify whether the delays were related to prior authorization (Hanna et al, 2020).

Summary of findings regarding the impact of prior authorization on health outcomes: There is *insufficient evidence* that prior authorization for biomarker testing impacts cancer outcomes for individuals with metastatic or advanced stage 3 or 4 cancer. No studies were identified that examined the impact of prior authorization for biomarker testing on remission rates, incidence of death, or survival rates. There is *limited evidence* that delays in receipt of systemic therapy, such as targeted therapy, impacts mortality risk for cancer; effects may vary by cancer type. To the extent that prior authorization delays biomarker testing, it could delay initiation of targeted therapies, which could increase mortality among persons with cancers for which targeted therapies are available.

Figure 3. Impact of Prior Authorization for Genetic Biomarker Testing on Health Outcomes

Figure 4. Impact of Delayed Systemic Therapy on Cancer Mortality Risk

Summary of Findings

Biomarker testing is an emerging tool that may be used in the treatment of advanced, metastatic, and stage 3 and 4 cancer, because it can help inform the provider's ability to customize treatment to a patient's genetic profile. However, there is currently *limited evidence* about the impact of prior authorization for biomarker testing on the timeliness of testing and treatment. There is currently insufficient evidence about the impact of prior authorization for biomarker testing on health outcomes.

CHBRP identified studies of the impact of prior authorization for various types of cancer medications and proton beam therapy. The study findings demonstrate that prior authorization practices vary by care setting and cancer type. Moreover, they demonstrate that most initial prior authorization requests for cancer medication are approved, and that requests that are initially denied are most often approved upon appeal. Findings regarding wait times for prior authorization approvals and prior authorization's impact on timeliness of initiation or receipt of care vary. One study found that delays in receiving biomarker test results could affect the ability to initiate first-line targeted therapies. None of the studies included in the literature review address the impact of prior authorization for genetic biomarker testing on health outcomes such as incidence of remission, incidence of death, and cancer survival rates. However, study findings demonstrate that delayed treatment increases cancer mortality. To the extent that prior authorization for biomarker testing delays initiation of targeted therapies, it could increase mortality among persons with cancers for which targeted therapies are available.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 535 would prohibit health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) from requiring prior authorization for biomarker testing for enrollees with stage 3 or 4 advanced or metastatic cancer.

In addition to commercial enrollees, more than 50% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 70% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[33] As noted in the *Policy Context* section, SB 535 would impact these CalPERS enrollees' but would not impact Medi-Cal beneficiaries' benefit coverage.

This section reports the potential incremental impacts of SB 535 on estimated baseline benefit coverage, utilization, and overall cost. Due to data limitations described below, CHBRP has provided an upper bound of potential impacts due to SB 535. CHBRP makes the following assumptions and approach decisions:

- To determine the number of enrollees with stage 3 or 4 cancer, CHBRP used the Centers for Disease Control and Prevention (CDC) Wonder Data, adjusted by the National Institute's SEER data. This results in an assumption that approximately 46% of enrollees with cancer have stage 3 or 4 cancer.
- CHBRP assumes each enrollee with stage 3 or 4 cancer would have a biomarker test. However, because biomarker testing is not recommended for all cancers or enrollees with stage 3 or 4 cancer, this assumption results in an overestimate of utilization.
    - One study that examined testing rates among enrollees with non-small cell lung cancer, for which there are multiple biomarker tests available, found between 88% and 100% of patients received at least one biomarker test (Mason et al., 2018). However, testing rates vary by type of cancer and biomarker (Pennell et al., 2019).
- Biomarker testing can be ordered individually or as part of a multibiomarker testing panel. CHBRP examined claims data for the cost of multibiomarker testing panels only. Because panels are more expensive than specific biomarker tests, the average cost per user may be overstated.
- CHBRP is unable to estimate how removing prior authorization for biomarker testing would lead to changes in cancer treatments and related outcomes. A qualitative discussion is provided in the *Public Health* section.

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

Baseline and Postmandate Benefit Coverage

Previous research has found that coverage for both single gene and multigene testing varies substantially across private health insurance plans and policies, and that there are discrepancies between coverage policies and clinical guidelines for such tests (Lu et al., 2018). Lu et al. also found that prior authorization was present in coverage for genetic biomarker tests for eight of the 10 private insurance payers that they studied (Lu et al., 2018).

At baseline, 100% of enrollees with health insurance that would be subject to SB 535 have benefit coverage for biomarker testing. Approximately 31% of enrollees have benefit coverage that requires prior authorization for biomarker testing. Of the 69% of enrollees with benefit coverage that does not require prior authorization at the plan level, prior authorization may be required at the provider level due to

[33] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.

provider group policies (e.g., a medical group could require its providers to submit prior authorization requests to the medical group, instead of to the health plan). CHBRP is unable to quantify this percent.

Postmandate, 100% of enrollees would have coverage for biomarker testing without prior authorization. However, SB 535 would not require coverage of biomarker testing that is considered experimental or if a plan or policy determines biomarker testing is not medically necessary. It is possible an enrollee would be denied coverage for biomarker testing postmandate due to these reasons, although CHBRP is unable to estimate this frequency. CHBRP assumed all tests denied during prior authorization would be covered postmandate, which may result in an overestimate of benefit coverage for biomarker testing.

Baseline and Postmandate Utilization

At baseline, approximately 15,902 enrollees receive biomarker tests (see Table 1). Approximately 4,851 enrollees have prior authorization requirements and 11,051 do not. The number of enrollees for whom authorization for biomarker testing is denied is 2,294. For enrollees denied approval for biomarker testing at baseline, CHBRP assumes 86.5% (1,985) would receive the biomarker test as a noncovered benefit.

Postmandate, the 4,851 enrollees with prior authorization requirements who receive the test at baseline, and an additional 309 enrollees who do not receive the test at baseline, would receive biomarker testing that is not subject to prior authorization requirements.

All of these enrollees would receive the biomarker test without prior authorization as a covered benefit. Reasons plans may deny coverage of biomarker testing includes the experimental nature of the test or biomarker, the biomarker test result would not be used to inform treatment decisions, or the biomarker test is not recommended for a specific type of cancer. CHBRP is unable to determine the reason authorization for biomarker tests may be denied and therefore assumes all of these tests would be a covered benefit postmandate. It is possible some biomarker tests may be denied coverage postmandate and an enrollee would pay out of pocket for the service. If the enrollee was not aware the test would be denied before they received the test, the enrollee may receive an unexpected bill.

Baseline and Postmandate Per-Unit Cost

The average cost of biomarker panel tests per user is $3,642 at baseline. This cost would not change postmandate.

Baseline and Postmandate Expenditures

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

SB 535 would increase total net annual expenditures by $2,506,000 or 0.0019% for enrollees with DMHC-regulated plans and CDI-regulated policies (see Table 1). This is due to a $7,753,000 increase in total health insurance premiums paid by employers and enrollees for covered benefits and a $1,979,000 increase in enrollee cost sharing for covered benefits, adjusted by a $7,226,000 decrease in enrollee expenses for noncovered benefits.

Premiums

Changes in premiums as a result of SB 535 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to SB 535.

Total PMPM premium increases range from a high of $0.15 for CDI-regulated individual market policies to a low of $0.03 for DMHC-regulated large-group plans.

Among publicly funded DMHC-regulated health plans, CalPERS HMOs would experience a total PMPM premium increase of $0.02.

Enrollee Expenses

SB 535–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6) with health insurance that would be subject to SB 535 expected to use the biomarker testing during the year after enactment.

CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of biomarker testing and therefore an increase in total enrollee cost sharing.

As mentioned above, it is possible that some enrollees incurred expenses related to biomarker testing for which coverage was denied. Based on information provided to CHBRP from a subset of plans and policies in California, CHBRP assumes 46% of prior authorization requests for biomarker testing are denied at baseline for enrollees with commercial coverage, and 14% of prior authorization requests for biomarker testing are denied at baseline for enrollees with coverage through CalPERS. Using the Milliman Health Cost Guideline induced utilization factors, CHBRP determined 86.5% of enrollees obtain the biomarker test and pay out of pocket for the noncovered service. The induced utilization factors are developed by examining utilization patterns based on annual costs of covered services. It is possible that fewer enrollees would want to pay out of pocket for a noncovered service. CHBRP is unable to quantify the share of enrollees that would be denied coverage of biomarker tests postmandate.

Enrollees with coverage for biomarker testing *without* prior authorization at baseline, on average, pay $612 in cost sharing. The average cost sharing for enrollees with coverage for biomarker testing *with* prior authorization at baseline is $835 (i.e., for enrollees for whom the prior authorization request was approved). Enrollees who are denied coverage for biomarker testing pay for the full cost of services out of pocket ($3,642 per biomarker panel). Postmandate, enrollees previously denied coverage for biomarker tests would receive the test without prior authorization and would only pay the applicable cost share. As a result, the average cost share for covered biomarker testing without prior authorization would increase to $687. The reason for the different average cost sharing amounts at baseline is due to the cost-sharing structure of plans and policies that include prior authorization requirements versus those that do not.

The decrease in out-of-pocket expenses for noncovered benefits results in costs shifting to premiums paid by employers and enrollees, and cost sharing for covered benefits.

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 in SB 535. CHBRP is unable to determine how or if treatments would change as a result of SB 535, and therefore what the impact would be on total expenditures.

Postmandate Administrative Expenses and Other Expenses

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

It is possible that administrative time spent by providers, medical offices, and health plans and policies would decrease, which could result in administrative cost savings.

Other Considerations for Policymakers

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

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 5, and Table 6), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 535.

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 535.

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

In general, CHBRP assumes that enrollees who do not have benefit coverage pay for biomarker testing directly (e.g., self-pay). However, in some cases, those noncovered benefits may be provided by public programs or by other, alternative sources. CHBRP is unable to quantify whether noncovered benefits are paid for by other programs or sources.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 535	8,405,000	2,086,000	1,989,000	889,000	0	0	384,000	43,000	144,000	13,940,000
Premiums										
Average portion of premium paid by employer	$426.28	$374.49	$0.00	$540.40	$226.61	$478.87	$530.80	$421.81	$0.00	$84,948,349,000
Average portion of premium paid by employee	$141.02	$180.89	$624.47	$96.86	$0.00	$0.00	$186.55	$212.07	$545.57	$36,600,954,000
Total premium	**$567.30**	**$555.38**	**$624.47**	**$637.27**	**$226.61**	**$478.87**	**$717.35**	**$633.88**	**$545.57**	**$121,549,303,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$43.61	$121.70	$173.51	$50.75	$0.00	$0.00	$134.75	$197.13	$184.11	$13,168,032,000
Expenses for noncovered benefits (e)	$0.02	$0.07	$0.08	$0.01	$0.00	$0.00	$0.14	$0.15	$0.15	$7,226,000
Total expenditures	**$610.93**	**$677.14**	**$798.06**	**$688.03**	**$226.61**	**$478.87**	**$852.23**	**$831.16**	**$729.83**	**$134,724,561,000**

Source: California Health Benefits Review Program, 2021.

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

(b) Approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) 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.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

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

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

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 535	8,405,000	2,086,000	1,989,000	889,000	0	0	384,000	43,000	144,000	13,940,000
Premiums										
Average portion of premium paid by employer	$0.0198	$0.0518	$0.0000	$0.0126	$0.0000	$0.0000	$0.1051	$0.0946	$0.0000	$3,960,000
Average portion of premium paid by employee	$0.0065	$0.0250	$0.0850	$0.0023	$0.0000	$0.0000	$0.0369	$0.0475	$0.1485	$3,792,000
Total premium	$0.0263	$0.0769	$0.0850	$0.0148	$0.0000	$0.0000	$0.1420	$0.1421	$0.1485	**$7,751,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$0.0037	$0.0227	$0.0301	$0.0021	$0.0000	$0.0000	$0.0362	$0.0551	$0.0603	$1,979,000
Expenses for noncovered benefits (e)	-$0.0225	-$0.0729	-$0.0849	-$0.0127	$0.0000	$0.0000	-$0.1358	-$0.1460	-$0.1549	-$7,226,000
Total expenditures	$0.0075	$0.0267	$0.0303	$0.0042	$0.0000	$0.0000	$0.0425	$0.0512	$0.0539	**$2,505,000**
Percent change										
Premiums	0.0046%	0.0138%	0.0136%	0.0023%	0.0000%	0.0000%	0.0198%	0.0224%	0.0272%	0.0064%
Total expenditures	0.0012%	0.0039%	0.0038%	0.0006%	0.0000%	0.0000%	0.0050%	0.0062%	0.0074%	0.0019%

Source: California Health Benefits Review Program, 2021.

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

(b) Approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) 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.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

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

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

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 535 would prohibit health plans and health policies from requiring prior authorization for biomarker testing for enrollees with stage 3 or 4 advanced or metastatic cancer.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[34] of SB 535 on timeliness of biomarker testing results, timeliness of cancer treatment, and disparities by race and ethnicity and income. See *Long-Term Impacts* for discussion of potential impacts beyond the first 12 months postmandate.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 535 include timeliness of biomarker testing and timeliness of cancer treatment.

As presented in the *Medical Effectiveness* section, there is limited evidence about the impact of prior authorization for biomarker testing on the timeliness of testing and treatment for individuals with metastatic or advanced stage 3 or 4 cancer. None of the studies included in the literature review address the impact of prior authorization on health outcomes such as incidence of remission, incidence of death, and cancer survival rates. However, there is limited evidence that delays in receipt of systemic therapy, such as targeted therapy, impacts mortality risk for cancer; effects may vary by cancer type. To the extent that prior authorization delays biomarker testing, it could delay initiation of targeted therapies, which could increase mortality among persons with cancers for which targeted therapies are available and effective.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, if all enrollees with stage 3 or 4 cancer receive a multibiomarker panel test without prior authorization, total net annual expenditures increase by $2,506,000 or 0.0019%. This is mostly due to a cost shift from enrollees paying out of pocket for denied biomarker tests at baseline to the tests being covered and the costs being split between premiums paid by employers and enrollees and enrollee cost sharing.

Prior Authorization

As mentioned in the *Policy Context* section, prior authorization is a utilization management tool health plans and policies use to ensure tests, treatments, or services are clinically appropriate. The high rates of prior authorization denials among enrollees requesting prior authorization for biomarker testing seems to indicate plans and policies are determining that these requests not clinically appropriate, at least initially. If the determinations are appealed and approved upon closer review, these denials could indicate prior authorization is leading to additional delays for medically necessary tests. The science behind biomarker testing and the relevant clinical recommendations are evolving. Additionally, providers who evaluate prior authorization requests for plans and policies may not be experts on biomarker testing, although they should have related expertise regarding oncology care. This could result in an initial denial of the prior authorization request, which may be subsequently approved upon appeal.

Should SB 535 be enacted, the removal of prior authorization assumes that all requests meet clinical standards for the test, which may not be the case. As a result, health expenditures would increase due to the increased number of tests paid for by the health plan or policy. It is unknown whether the increase in covered biomarker testing leads to improvements in time to treatment initiation or related health outcomes.

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

However, the removal of prior authorization for biomarker testing would enable the patient to receive the test and test result more quickly by eliminating the time it takes the provider to prepare and submit the request, and eliminating the time the health plan or policy takes to evaluate the request and issue decision.

Time to Treatment Initiation

As mentioned in the *Background* section, delays in time to treatment initiation for new cancer diagnoses are commonly known to cause patient anxiety and for many cancers, increased time to treatment initiation is associated with worsened survival. The largest associations were seen in pancreas and non-small cell lung cancer (NSCLC), two cancers for which there are biomarker tests that can impact treatment decisions (Khorana et al., 2019). Lung cancer is the leading cause of death in California and the world, while pancreatic cancer also has a high mortality rate once diagnosed. Should prior authorization for biomarker testing lead to at least a week of delay in treatment, there is the potential to see increased risk of death.

Wong et al. (2020) found patients for whom test results for the ROS1 biomarker were delayed at least 25 days after diagnoses were almost 10 times more likely to initiate treatment (such as chemotherapy) prior to receiving the test results. Whether the treatment decisions were solely a result of the delay in receipt of the test results is unclear but possible. The authors did not evaluate whether this delay in receipt of test results or the initiation of other treatments resulted in poorer health outcomes.

Cancer care is complex and there are many factors that impact testing and treatment decisions. While the removal of prior authorization has the potential to decrease time to treatment, there is no evidence that evaluates this directly.

Because there is insufficient evidence of the impact of prior authorization on biomarker testing, the public health impact of SB 535 is unknown. Please note that the absence of evidence is not "evidence of no effect." It is possible that an impact — desirable or undesirable — could result, but current evidence is insufficient to inform an estimate.

However, there is some evidence that delays in testing results impact treatments delivered for cancer, and that delays in treatment may lead to poorer health outcomes (Wong et al., 2020). Should SB 535 result in fewer delays in obtaining biomarker test results, there is the potential for a limited public health impact.

Impact on Disparities[35]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in incidence of cancer and rates of biomarker testing exist by race and ethnicity and income. Within the first 12 months postmandate, CHBRP estimates SB 535's removal of prior authorization is unlikely to change racial and ethnic disparities. If previously denied biomarker testing is a covered benefit postmandate, there is the potential for disparities by income to decrease. (For a discussion of potential impacts beyond the first 12 months of implementation [including SDoH], see *Long-Term Impacts*.)

[35] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

Impact on Racial or Ethnic Disparities

As mentioned in the *Background* section, there are disparities in rates of biomarker testing by race and ethnicity. In particular, biomarker testing rates are lower for Black and Hispanic persons compared to White persons and Asian and Pacific Islander people.

The impact of SB 535 on reducing documented disparities among racial and ethnic groups (see the *Background* section) is unknown because data are unavailable to estimate the impact of the removal of prior authorization on rates of biomarker testing. However, it stands to reason that if prior authorization was the sole barrier for some enrollees, SB 535 could result in a reduction in racial and ethnic disparities in testing rates.

Income

CHBRP also found evidence of disparities in rates of biomarker testing by income, with people of lower socio-economic levels receiving biomarker testing at lower rates. If the prior authorization request is denied and the patient would be required to pay for the full cost out of pocket, enrollees with lower incomes may choose to forgo the biomarker test due to cost. If previously denied biomarker tests would be covered postmandate, an enrollees would not be required to pay the full cost of the test out of pocket (but would still be responsible for the average $687 cost share), disparities in testing rates by income could be ameliorated. However, should coverage for the biomarker test be denied after it is performed, an enrollee could face a large and unexpected medical bill, which could create a financial hardship, especially for low-income enrollees.

SB 535 could result in a reduction of income disparities in biomarker testing rates due to a decrease in coverage denials for biomarker tests; however, the degree to which these disparities may decrease is unknown.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 535, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

The impacts of SB 535 are unlikely to be different in subsequent years, assuming the same number of biomarker tests and targeted therapies are available. However, changes in clinical recommendations regarding biomarker testing and the availability and number of biomarker tests may lead to increased utilization of biomarker testing. The number of oncology drug approvals, including those for gene-targeted therapy, have been increasing over the last decade (Vadas et al., 2019). And, there are anticipated changes in biomarker testing recommendations and targeted treatments for cancers, pending FDA approval.[36]

Cost Impacts

Similarly, the potential expenditure increases as a result of the removal of prior authorization for biomarker testing are likely to be similar in subsequent years. As mentioned above, changes in the clinical recommendations regarding biomarker testing and the type and number of biomarker tests available could impact overall and per-unit costs.

Long-Term Public Health Impacts

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

In the case of SB 535, CHBRP estimates the change in utilization would be similar to those experienced in the first year postmandate; therefore, the long-term public health impacts are also similar.

Impacts on Disparities and the Social Determinants of Health[37]

While there is evidence that disparities in biomarker testing rates by race and ethnicity and income exist, there is insufficient evidence to determine whether SB 535 will ameliorate these disparities and lead to improved health outcomes in the long term.

[36] Personal communication with K Kelly, MD, on March 30, 2021.
[37] For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses* at http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

APPENDIX A TEXT OF BILL ANALYZED

On February 19, 2021, the California Senate Committee on Health requested that CHBRP analyze SB 535.

SENATE BILL **NO. 535**

Introduced by Senator Limón
(Principal coauthors: Assembly Members Friedman and Lorena Gonzalez)

February 17, 2021

An act to amend Section 1367.665 of the Health and Safety Code, and to amend Section 10123.20 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 535, as introduced, Limón. Biomarker testing.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires an individual or group health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after July 1, 2000, to provide coverage for all generally medically accepted cancer screening tests.

This bill would prohibit an individual or group health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after January 1, 2022, from requiring prior authorization for biomarker testing for an enrollee or insured with advanced or metastatic stage 3 or 4 cancer. The bill would also prohibit those individual or group health care service plans or health insurance policies from requiring prior authorization for biomarker testing for cancer progression or recurrence in the enrollee or insured with advanced or metastatic stage 3 or 4 cancer.

Because a willful violation of these provisions by a health care service plan 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 Local Program: yes

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

SECTION 1. Section 1367.665 of the Health and Safety Code is amended to read:

1367.665. Every (a) An individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply.

(b) An individual or group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2022, shall not require prior authorization for either of the following:

(1) Biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer.

(2) Biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

(c) For purposes of this section, "biomarker test" means a diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer, in order to guide patient treatment.

SEC. 2. Section 10123.20 of the Insurance Code is amended to read:

10123.20. (a) ~~Every~~ *An* individual or group ~~disability~~ *health* insurance policy ~~that covers hospital, medical, or surgical expenses~~ that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all other terms and conditions that would otherwise apply.

(b) An individual or group health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2022, shall not require prior authorization for either of the following:

(1) Biomarker testing for an insured with advanced or metastatic stage 3 or 4 cancer.

(2) Biomarker testing of cancer progression or recurrence in the insured with advanced or metastatic stage 3 or 4 cancer.

(c) For purposes of this section, "biomarker test" means a diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer, in order to guide patient treatment.

~~(b)~~

(d) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, or disability income insurance, except that for accident-only, specified disease, or hospital indemnity insurance, coverage for benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. ~~Nothing in this section shall~~ *This section shall not* be construed as imposing a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

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

CHBRP had previously conducted thorough literature searches on these topics in 2020 for AB 2640. That search did not return any literature specifically on prior authorization for genetic biomarker testing for advanced, metastatic, or stage 3 and 4 cancer. A new literature search was conducted for SB 535.

Studies of genetic biomarker testing for advanced, metastatic, or stage 3 or 4 cancer were identified through searches of PubMed, EMBASE, Web of Science, Cochrane Library from 2020 to the present, and the website of the National Comprehensive Cancer Network.

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

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

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 39 articles, of which three were reviewed for inclusion in this report. Four additional articles were identified through subsequent research. A total of seven studies were included in the medical effectiveness review for SB 535.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[38] 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.*

[38] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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

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

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

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

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

Search Terms (* indicates truncation of word stem)

- Access to Biomarker Testing
- Advanced Cancer
- ALD
- ALK
- barriers
- BCR-ABL1
- Biomarkers, Tumor
- BRAF
- BRCA-1/2
- BRCA-2
- Carcinoma, Non-Small-Cell Lung
- CD20
- CD25
- c-Kit Protein
- Death
- EGFR
- ERBB2/HER2
- Ethnic Groups
- Ethnicity
- G6PD
- Genetic Biomarker Testing
- Genetic Markers
- Genetic Testing
- Genomic test*
- Harms
- Health Services Accessibility
- Healthcare Disparities
- HER2
- Incidence
- Initiation
- Insurance approval
- KRAS
- MET
- Metastatic Cancer
- Molecule Targeted Therapy
- Mortality
- Multi-gene testing
- Neoplasm Metastasis
- Neoplasm Staging
- NTRK
- PDGFR
- Pharmacogenetic Testing
- Pharmacogenetics
- PML RARA
- Pre-Authorization
- Prevalence
- Prior Authorization
- Race
- Race Factors
- Racial Disparities
- Remission
- RET
- ROS1
- Stage 3 Cancer
- Stage 4 Cancer
- Survival Rate
- Targeted Therapy
- Time to treatment
- Timeliness
- Treatment delay*
- Tumor Marker

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

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[39] 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.[40]

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

Analysis-Specific Data Sources

Current coverage of biomarker testing with and without prior authorization for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 73% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS HMO plans were queried regarding related benefit coverage.

CHBRP uses Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD) to estimate average cost for biomarker testing in 2022.

Analysis-Specific Caveats and Assumptions

Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- CHBRP assumed 100% of the population subject to mandated offerings currently offer some form of coverage for biomarker testing for enrollees with stage 3 or 4 cancer and are subject to SB 535.

Assumptions for Baseline Utilization and Cost

- The average cost for biomarker tests are based on the 2019 Consolidated Health Cost Guidelines Sources Plus Database (CHSD+). The data was limited to California commercial enrollees. CHBRP summarized the average allowed cost per user of biomarker tests as it is possible for some users to have more than one test performed.
- Biomarker testing can be performed for a single biomarker or in a panel for several biomarkers. CHBRP only included panels in the analysis. Because panels are more expensive than specific biomarker tests, the average cost per user may be overstated. The procedure codes used to identify biomarker tests are listed in Table 7 below.
- Average allowed cost per user was trended from 2019 to 2022 using 4.5% trend.
- Cancer prevalence in the population was determined using Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) 1999-2017

[39] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[40] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2021 Cost Analyses: Data Sources, Caveats, and Assumptions*.

Incidence data for the state of California. The incidence rates were developed for the 0 to 17, 18 to 64, and 65+ age groups.

- Incidence of stage 3 and 4 cancer was developed using data from the National Cancer Institute's Surveillance, Epidemiology and End Results Program (SEER) data for the 2010–2016 period. CHBRP assumed the regional and distant cancers were stage 3 and 4. The stages were reported by 0 to 64 and 65+ age groups.
- CHBRP assumed that each person with a stage 3 or 4 cancer would have a biomarker test. Not all cancers or people with cancer could benefit from having a biomarker test. Assuming that each person gets a biomarker test will overstate the total utilization.
- CHBRP conducted a carrier survey to determine the percentage of enrollees subject to prior-authorization of biomarker tests for enrollees with stage 3 or 4 cancer. In many cases, carriers responded that they require prior authorization for some tests but not others. CHBRP assumed that if they have any prior authorization it was for 100% of the biomarker tests. This results in a high-end estimate of tests subject to prior authorization.
- CHBRP conducted a carrier survey to determine the percentage of enrollees who had a prior authorization request denied. Of the denials, the carriers were unable to determine who had a stage 3 or 4 cancer. CHBRP assumed the denial rate as indicated in the surveys. It is possible that the denial rate for those with stage 3 or 4 cancer is different than the reported denial rate.
- CHBRP assumed 86.5% of users who have prior authorization and are denied a test receive the test and pay for it out of pocket. CHBRP's assumption is based on Health Cost Guidelines induced utilization factors.

Table 7. Procedure Codes Used to Identify Biomarker Tests

CPT/HCPCS	Long Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81479	Unlisted molecular pathology procedure

Assumptions for Baseline Cost Sharing

- For users without prior authorization or users who have prior authorization and the biomarker test was approved, CHBRP developed the cost-share amount using the paid-to-allowed ratios for biomarker tests from the CHSD+ database. To adjust for average plan benefit differentials by line of business, factors were calculated by comparing paid-to-allowed ratios of each line of business to the overall paid-to-allowed ratios of the California commercial population in the CHSD+ database. The biomarker test paid-to-allowed ratios were multiplied by the line of business factors to calculate line of business-specific biomarker test paid-to-allowed ratios. One minus the line of

business adjusted paid-to-allowed ratio was applied multiplicatively to the allowed cost to determine the enrollee share of cost for users who were not denied the biomarker test.

- For users denied the biomarker test, CHBRP assumed their cost share is equal to the total allowed cost per user.

Assumptions for Postmandate Utilization

- For users without prior authorization or users who have prior authorization and the biomarker test was approved, CHBRP did not assume utilization would increase as a result of SB 535.
- For users with prior authorization who were denied the biomarker test, CHBRP assumed 100% of them would receive the biomarker test.

Assumptions for Postmandate Cost

- CHBRP did not assume biomarker test costs would increase as a result of SB 535.

Assumptions for Postmandate Cost Sharing

- For users without prior authorization or users who have prior authorization and the biomarker test was approved, the cost sharing would not change as a result of SB 535.
- For users with prior authorization who were denied the biomarker test in the baseline, CHBRP followed the methodology outlined in the "Assumptions for Baseline Cost Sharing" section for the users without prior authorization or users who have prior authorization and the biomarker test was approved.
- It is possible that users who are denied prior authorization in the baseline are denied the biomarker test because the service is considered experimental. Experimental services are not typically covered under health insurance policies. It is possible that these users would not know that the biomarker test is experimental prior to receiving the test and would receive a bill for the entire cost of the biomarker test. CHBRP's analysis assumes that these biomarker tests would be covered, and users are only paying a portion of the biomarker test. Actual cost sharing may be higher than what is modeled.

Determining Public Demand for the Proposed Mandate

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 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 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 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.

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

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 535 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed; the utilization of any indirectly affected utilization; or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second-year impacts of SB 535 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. 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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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