Key Findings

Analysis of California Senate Bill 535 Biomarker Testing

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

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

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

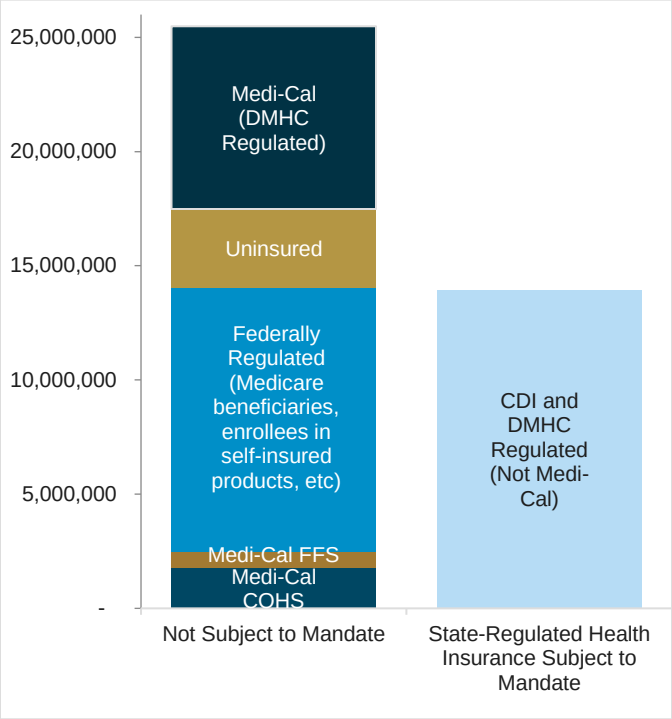
SB 535 would prohibit individual and group plans and policies from requiring prior authorization for biomarker testing for:

- 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.

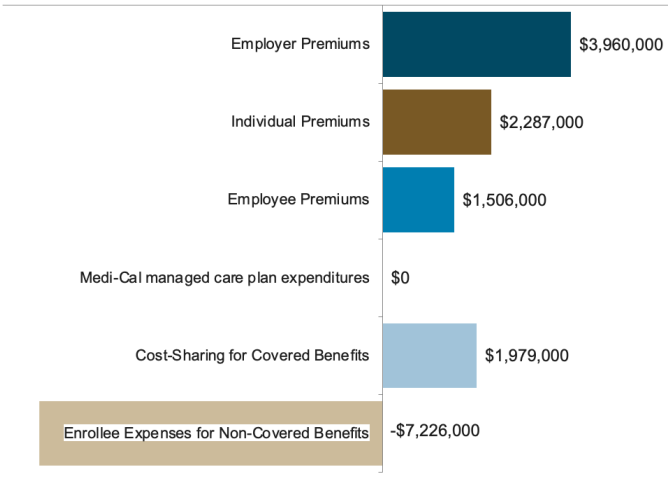
Expenditures

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.