SENATE COMMITTEE ON HEALTH
Senator Dr. Susan Talamantes Eggman, Chair

BILL NO: SB 496
AUTHOR: Limón
VERSION: February 14, 2023
HEARING DATE: April 19, 2023
CONSULTANT: Teri Boughton

SUBJECT: Biomarker testing

SUMMARY: Requires a health plan contract or a health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2024, to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's or insured's disease or condition to guide treatment decisions only if the test is supported by medical and scientific evidence, as specified.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act); California Department of Insurance (CDI) to regulate health and other insurance; and, the Department of Health Care Services (DHCS) to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., and WIC §14000, et seq.]

2) Covers as a Medi-Cal benefit for one year olds and younger who are receiving inpatient hospital services in an intensive care unit Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing. [WIC §14132]

3) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services to:

    a) Be developed with involvement from actively practicing health care providers;
    b) Be consistent with sound clinical principles and processes;
    c) Be evaluated, and updated if necessary, at least annually;
    d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
    e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

4) Requires a health plan contract and health insurance policy, except for a specialized health plan contract and policy, to be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply. [HSC §1367.665 and INS §10123.20]

5) Prohibits a health plan contract and health insurance policy, except for a specialized health plan contract and policy from requiring prior authorization for either of the following:

    a) Biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer; or,

b) Biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer. [HSC §1367.665 and INS §10123.20]

6) Applies 3) above to health plan contracts and Medi-Cal managed care plan contracts with DHCS. [HSC §1367.665 and INS §10123.20]

7) Defines "biomarker test" for purposes of 4) above as a diagnostic test, such as single or multigene, of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment. [HSC §1367.665 and INS §10123.20]

8) States that 4) above does not prohibit a health plan or insurer from requiring prior authorization on biomarker testing that is not for an United States Food and Drug Administration (FDA) FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer, and does not limit, prohibit, or modify an enrollee's or insured's rights to biomarker testing as part of an approved clinical trial under existing law. [HSC §1367.665 and INS §10123.20]

9) Requires every health plan to establish and maintain a grievance system approved by DMHC under which enrollees may submit grievances to the plan. Requires a plan's response to also comply with federal requirements. [HSC §1368]

10) Establishes an independent medical review (IMR) process, under which enrollee and insured grievances involving a disputed health care service are eligible for review. Defines "disputed health care service" as any health care service eligible for coverage and payment under the contract that has been denied, modified, or delayed by a decision of the plan, or contracting provider, in whole or in part due to a finding that the service is not medically necessary. [HSC §1374.30 and INS §10169]

11) Establishes a process for expeditiously reviewing IMR requests related to imminent and serious threat to the enrollee. [HSC §1374.31 and INS §10169.1]

12) Requires under federal law a group health plan and a health insurance issuer offering group or individual health insurance coverage to implement an effective appeals process for appeals of coverage determinations and claims, including an internal claims appeal process with notices in a culturally and linguistically appropriate manner, of available internal and external appeals process. Establishes processes for internal and external reviews. [42 USC §300gg-19]

This bill:

1) Requires a health plan contract, except for a specialized health plan contract, or a health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2024, to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's or insured's disease or condition to guide treatment decisions only if the test is supported by medical and scientific evidence. Defines, "medical and scientific evidence" as one or more of the following:

a) A labeled indication for a test that has been approved or cleared by the FDA or is an indicated test for an FDA-approved drug;

b) A national coverage determination made by the federal Centers for Medicare and Medicaid Services;
c) A local coverage determination made by a Medicare Administrative Contractor; or,
d) Evidence-based, nationally recognized clinical practice guidelines and consensus statements.

2) Requires the health plan or health insurance policy to ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples, but this bill does not require coverage of biomarker testing for screening purposes unless otherwise required by law.

3) Subjects restricted use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition to grievance and appeal processes under state and federal law.

4) Applies this bill to any health plan contract and Medi-Cal managed care plan contract, or insurance policy with DHCS.

5) Exempts 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 bill to 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. States that this bill does not impose a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

6) Establishes the following definitions:

a) "Biomarker" is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention. A biomarker includes, but is not limited to, gene mutations or protein expression;
b) "Biomarker testing" is the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing;
c) "Consensus statements" are statements developed by an independent, multidisciplinary panel of experts who utilize a transparent methodology and reporting structure, and are subject to a conflict of interest policy. These statements are aimed at specific clinical circumstances and are based on the best available evidence to optimize the outcomes of clinical care; and,
d) "Nationally recognized clinical practice guidelines" are evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure, and are subject to a conflict-of-interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options, and those guidelines include recommendations intended to optimize clinical care.

7) Applies the provisions described above to the Medi-Cal program subject to utilization controls, and only to the extent federal financial participation is available and not otherwise

jeopardized, and any necessary federal approvals have been obtained. Permits DHCS to implement this bill by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* According to the author, this bill requires a health plan and health insurance policy issued, amended, or renewed on or after July 1, 2024, to provide coverage for biomarker testing. Precision medicine improves patient outcomes by using their own genes or proteins (biomarkers) to prevent, diagnose, or treat diseases. Biomarker testing can be performed for cancer, including prostate, ovarian, colorectal, breast, and lung cancers; Alzheimer's disease; rheumatoid arthritis, type 2 diabetes; and other conditions. Timely care is vital for patients to treat their disease, slow disease recurrence or progression, and improve their quality of life. Targeted treatments will improve survival rates and reduce costs by connecting patients to the most effective treatments. This bill will improve access to biomarker testing, ensuring patients receive the right treatment at the right time.

2) *California Health Benefits Review Program (CHBRP) analysis.* AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996, and conducted an abbreviated review of SB 912 (Limón of 2022), which is similar to this bill. Key findings include:

    a) *Background.* According to CHBRP, biomarker is a characteristic that can be measured to specify normal or abnormal health processes or to indicate a condition or disease. These measurements can also be used to determine the effects a treatment is having on a patient. Biomarker tests are a way to measure and quantify biomarkers. Nonphysiologic tests are often done in a laboratory using samples of blood, tissue, or other clinical samples to quantify and evaluate the biomarker. In recent years, biomarker testing has been used in the expansion of precision medicine, an approach in which treatment and prevention are based on patients' genetic, environmental, and lifestyle factors rather than a single approach to a disease or condition for all patients. Biomarkers can be tested a variety of ways, including through common blood biomarker tests, individually (single-analyte tests), within a multiplex panel test, or as part of whole genome or exome sequencing. Biomarker testing can be performed for cancer including prostate, ovarian, colorectal, breast, and lung cancers; Alzheimer's disease; rheumatoid arthritis; type 2 diabetes; and other conditions. Additionally, many biomarkers may be associated with several diseases and conditions. Performing biomarker testing for cancer, for example, enables a provider to accurately match the therapy to an individual patient by focusing on treatments most likely to be effective, and decreases treatment harms by avoiding treatments that are unlikely to result in improvement (e.g., chemotherapy), or may result in an adverse reaction. Biomarker tests can be used across the continuum of care for many diseases and conditions for the purposes of screening asymptomatic individuals, determining the presence of disease (diagnosis), estimating the risk or time to clinical outcomes (prognosis), identifying the likelihood of a patient to benefit from certain therapies (predictive) and to experience therapy-related risks (pharmacogenomics), or for treatment monitoring purposes.

b) *Coverage impacts and enrollees covered.* If enacted, the bill would apply to the health insurance of approximately 24.5 million enrollees (62.3% of all Californians). This represents enrollees in plans regulated by DMHC and policies regulated by the CDI, as well as Medi-Cal beneficiaries enrolled in County Organized Health Systems (COHS) or whose benefits are administered by DHCS. According to CHBRP there may be some variation in coverage of biomarker testing at baseline, but CHBRP is unable to identify which biomarker tests may not be currently covered.

c) *Benefit Coverage.* CHBRP indicates that broadly speaking, all enrollees with health insurance subject to this bill have coverage for biomarker testing that is supported by medical and scientific evidence and is determined medically necessary. There may be some biomarker tests that are newly covered based on the implementation of this bill, but CHBRP is unable to determine to which biomarker tests this applies.

d) *Utilization and expenditures*. Because this bill would not result in changes in benefit coverage, there would be no changes in utilization of biomarker tests or changes in health care expenditures as a result of this bill. More than 200,000 commercial and CalPERS enrollees and 100,000 Medi-Cal beneficiaries use biomarker testing each year. Some enrollees may use multiple forms of biomarker testing. Utilization of biomarker testing per 1,000 commercial and CalPERS enrollees is 14 for single-analyte tests, 3.2 for multiplex panel tests, and 0.4 for whole exome or genome sequencing. Utilization of biomarker testing per 1,000 Medi-Cal beneficiaries is 10.3 for single-analyte tests, 2.3 for multiplex panel tests, and 0.4 for whole exome or genome sequencing. Because biomarker testing is already broadly covered, utilization is not expected to change as a result of the passage of this bill. The average annual cost per user of biomarker testing for enrollees with commercial or CalPERS coverage was $677 for single-analyte tests, $948 for multiplex panel tests, and $984 for whole exome or genome testing. The average annual cost per user of biomarker testing for Medi-Cal beneficiaries was $426 for a single-analyte test, $460 for a multiplex panel test, and $488 for whole exome or genome testing. The average annual cost-sharing for commercial and CalPERS enrollees using biomarker testing ranges between $64 and $90. CHBRP indicates this bill would not result in changes to benefit coverage and therefore no resulting changes in utilization of biomarker tests and related treatments, it is important to understand how use of biomarker tests may lead to other health care utilization and expenditure impacts.

e) *Medical effectiveness.* Several studies have found biomarker-driven treatment improves treatment outcomes, including survival rate, and may also be cost-effective, leading to elimination of costs for other less-targeted therapies or offsets in the form of reduced emergency department and in-patient hospital admission. However, the clinical effectiveness of biomarker tests and related treatments varies based on the disease or condition and patient characteristics. Clinical guidelines are one source of information about the effectiveness of biomarker testing and related treatments. Due to the number of biomarker tests, CHBRP is unable to conduct a medical effectiveness review of biomarker testing within its 60-day timeline.

f) *Health disparities and social determinants of health.* Literature indicates that the disparities in testing by race or ethnicity, age, and socio-economic status could widen inequities in utilization of biomarker testing if not specifically addressed. Additionally, studies have suggested that clinician barriers — including familiarity with guidelines and knowledge of best practices for use of biomarker testing, expertise in genomic testing, or access to a multidisciplinary specialty team — impact whether patients receive testing.

g) *Essential Health Benefits (EHBs).* Under existing law, plans and policies are required to cover medically necessary diagnostic lab services and ongoing disease management services. Additionally, biomarker testing is broadly covered by California's EHB

benchmark plan. Because this bill would not require coverage for a new state benefit mandate, it therefore appears not to exceed the definition of EHBs in California.

h) Long-term implications. CHBRP assumes it is likely that plans and policies will continue to incorporate new clinical guidelines as they become available in future years. While not directly related to this bill, there are implications for health plans and policies, including Medi-Cal, as new biomarker tests become available and new therapies indicated by biomarker testing become available. Some medications with biomarker-indications cost more than $100,000 annually. Although utilization of these high-cost medications is relatively low, should utilization increase, related health care expenditures would increase as well. As noted previously, evidence supports clinical utility and cost-effectiveness of several biomarker tests and related treatments, which could contribute to offsets in health care expenditures or improved quality of life for enrollees.

3) *Related legislation.* AB 700 (Grayson) requires the Department of Public Health to award grants to eligible educational institutions to conduct research using a fire service community-based participatory research model that includes the understanding of biomarkers of exposure and studying biomarkers of effect that quantify cancer-promoting cellular changes that ultimately lead to a cancer diagnosis. *AB 700 passed out of the Assembly Health Committee on March 29, 2023 on 14-0 vote.*

4) *Prior legislation.* SB 912 (Limon of 2022) would have required health plan contracts, disability insurance policies, and Medi-Cal to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring if the test is supported by medical and scientific evidence, as specified. *SB 912 was vetoed by the Governor, who stated:*

> *This bill would require health care service plans, including the Medi-Cal program, to provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a person's disease or condition, as long as the test is supported by medical and scientific evidence, as defined in the bill.*
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> *While I appreciate the author's efforts to provide biomarker testing coverage, these services are already covered by Medi-Cal. Furthermore, biomarker testing is valuable when it can inform a condition's diagnosis and treatment, but this bill would require Medi-Cal to cover unnecessary testing that may not inform the best treatment to care for the beneficiary.*
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> *For example, this bill would require the Department of Health Care Services (Department) to cover biomarker testing supported by local coverage determinations, which can contradict each other, and tests supported by "nationally recognized clinical practice guidelines and consensus statements," which may not be evidenced-based. In contrast, Medi-Cal policy is based upon the gold standard of guidelines with standards set by the National Academy of Medicine.*
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> *This bill would establish broad and contradictory coverage requirements that go beyond the Department's evidence-based policies, which would unnecessarily increase costs without increasing the quality of coverage. I believe the Department should retain its current flexibility to establish evidence-based policies in light of the dynamic and changing nature of medicine.*

SB 535 (Limón, Chapter 605, Statutes of 2021) prohibits health plans and insurers from requiring prior authorization for biomarker testing for advanced or metastatic stage 3 or 4 cancer, and cancer progression or recurrence.

5) *Support.* According to the American Cancer Society Cancer Action Network and University of California, cosponsors of this bill, cancer biomarkers can include molecules like proteins or genetic alterations such as mutations, rearrangements, or fusions. Testing patients for specific biomarkers is integral to precision medicine in cancer care but, despite evidence pointing to the clinical benefits associated with biomarker testing, routine clinical use does not always follow, and testing rates lag behind clinical guideline recommendations. In a 2021 survey, 66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing. Insurance coverage for biomarker testing is failing to keep pace with innovations and advancements in treatment. This bill will require state-regulated insurance plans, including Medi-Cal, to cover comprehensive biomarker testing when supported by medical and scientific evidence, including nationally recognized clinical practice guidelines. Timely access to appropriate biomarker testing can help achieve better health outcomes, improve quality of life and reduce costs by connecting patients to the most effective treatment for their cancer. The Crohn's and Colitis Foundation write procedures, like colonoscopy, help diagnose and evaluate irritable bowel syndrome, which is very helpful, but also invasive, expensive, and carries some risk; and fail to answer all questions. As irritable bowel syndrome biomarkers become available, coverage should not be a barrier for patients to receive biomarker testing when being treated. This bill removes this impediment by ensuring health plans provide coverage for this important testing.

6) *Opposition unless amended.* The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) write that this bill inadvertently requires health plans and insurers to cover biomarker testing in a way that will increase healthcare costs while potentially subjecting patients to lower levels of care. Biomarker testing is a broad category. While this category includes some tests that are the current standard of care, it includes others that are still classified as experimental. This is also a field that is rapidly expanding as new tests are frequently developed. Health plans and insurers work to ensure the patient meets the criteria for the test and the appropriate test is being ordered. Many testing companies have created large panels of tests that are often denied because a single test is really all that is medically necessary. This bill would require coverage of unnecessary testing which creates waste and potential harm to the patient. Prematurely opening the door to more testing mandates, with little proven benefit, will raise the cost of healthcare while providing very little benefit to patients. Further, reducing a plan or insurer from having oversight with respect to these types of services may incentivize testing companies to market large expensive panels of tests that far exceed what is needed in a particular case. CAHP and ACLHIC request an amendment to ensure that only those tests which are deemed to be both evidence based and medically necessary be covered.

7) *Amendments.* CDI has requested amendments to the Insurance Code to do the following:
   a) Subdivision (b) replace "chapter" with "part"
   b) Subdivision (c) add ***including Section 2719 of the federal Public Health Service Act (Sec. 300gg-19 of Title 45 of the United States Code) and any regulations subsequently adopted thereunder, and the Independent Medical Review System under Article 3.5 of Chapter 1 of Part 2 of Division 2 (commencing with section 10169).***
   c) Subdivision (d) delete the entire subdivision.

d) Subdivision (e) amend the subdivision to limit the exemption from the bill to vision-only, dental-only, or Medicare supplement insurance. According to CDI these are the only exemptions needed.
e) CAHP and ACLHIC have requested an amendment to add that covered biomarker testing is medically necessary.
f) In response to these requests the author asks the committee adopt amendments reflected in a)-d) above, and, the following (for health plans and insurers) to address the CAHP and ACLHIC request:
(a) A 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, 2024, shall cover **medically necessary** biomarker testing pursuant to this section. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions only if the test is supported by medical and scientific evidence. For purposes of this subdivision, "medical and scientific evidence" means one or more of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services.

(3) A local coverage determination made by a Medicare Administrative Contractor.

(4) Evidence-based, nationally recognized clinical practice guidelines and consensus statements.

(b) **For purposes of this section, "medically necessary" shall be developed using the process described in 1363.5 and at a minimum, shall include the criteria in subdivision (a).**

SUPPORT AND OPPOSITION:

Support: American Cancer Society Cancer Action Network (cosponsor)
University of California (cosponsor)
Advanced Medical Technology Association
Alliance for Patient Access
Association of Regional Center Agencies
Biocom California
Biogen
Biotechnology Innovation Organization
California Chronic Care Coalition
California Clinical Laboratories Association
California Life Sciences
California Manufacturers & Technology Association
California Medical Association
Children's Specialty Care Coalition
City of Hope
Crohn's and Colitis Foundation

GSK
MiOra
Natera
The Michael J. Fox Foundation for Parkinson's Research

Oppose: America's Health Insurance Plans
Association of California Life and Health Insurance Companies (unless amended)
California Association of Health Plans (unless amended)

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