
UNFINISHED BUSINESS

Bill No: SB 496
Author: Limón (D), et al.
Amended: 9/7/23
Vote: 21

SENATE HEALTH COMMITTEE: 11-0, 4/19/23
AYES: Eggman, Nguyen, Dahle, Glazer, Gonzalez, Limón, Menjivar, Roth,
Rubio, Wahab, Wiener
NO VOTE RECORDED: Hurtado

SENATE APPROPRIATIONS COMMITTEE: 6-0, 5/18/23
AYES: Portantino, Jones, Ashby, Bradford, Wahab, Wiener
NO VOTE RECORDED: Seyarto

SENATE FLOOR: 40-0, 5/24/23
AYES: Allen, Alvarado-Gil, Archuleta, Ashby, Atkins, Becker, Blakespear,
Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez,
Grove, Hurtado, Jones, Laird, Limón, McGuire, Menjivar, Min, Newman,
Nguyen, Niello, Ochoa Bogh, Padilla, Portantino, Roth, Rubio, Seyarto, Skinner,
Smallwood-Cuevas, Stern, Umberg, Wahab, Wiener, Wilk

ASSEMBLY FLOOR: 79-0, 9/13/23 - See last page for vote

SUBJECT: Biomarker testing

SOURCE: American Cancer Society Cancer Action Network
University of California

DIGEST: This bill requires Medi-Cal, and, a health plan contract or a health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2024, and Medi-Cal, to cover medically necessary 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.

Assembly Amendments:

- 1) Require coverage for medically necessary biomarker testing to be subject to utilization controls.
- 2) Delete the requirement that the decision to test must be supported by medical and scientific evidence, as defined in this bill; and, instead requires coverage to include biomarker tests that meet one of the criteria in this bill.
- 3) Revise the criteria to ensure Medicare Administrative Contractor determinations must be those for California, and evidence-based clinical practice guidelines must be supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff. Add a criterion that includes standards set by the National Academy of Medicine.
- 4) Allow denied use of biomarker testing to be subject to grievance and appeal processes under state and federal law.
- 5) Require DHCS to direct, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, that biomarker testing is to be provided in a manner that limits disruptions in care.
- 6) Require the all-county letter, plan letter, plan or provider bulletin, or similar instructions issued by the Department of Health Care Services (DHCS) to be based at a minimum on evidence-based, nationally recognized clinical practice guidelines, and may be based on consensus statements.

ANALYSIS:

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, DHCS to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., and WIC §14000, et seq.]
- 2) 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]

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

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 medically necessary 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 that meets any 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 for California;
 - d) Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; or,

- e) Standards set by the National Academy of Medicine.
- 2) Requires a health plan or health insurer to use a specified process to determine whether biomarker testing is medically necessary.
 - 3) 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.
 - 4) Applies substantially similar 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.

Comments

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 improves access to biomarker testing, ensuring patients receive the right treatment at the right time.

California Health Benefits Review Program (CHBRP) analysis. AB 1996 (Thomson, Chapter 795, Statutes of 2002) requested 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, 2022), which is similar to this bill.

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.

Related/Prior Legislation

SB 912 (Limon, 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.

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.

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.

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.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Appropriations Committee,

- CDI estimates this bill will cost \$22,000 in fiscal year (FY) 2024-25 to review forms submitted by insurers (Insurance Fund).
- DMHC estimates additional workload to address an increase in consumer complaints; revise survey methodology and compliance monitoring tools, including reviewing health plans' utilization management processes and providing guidance to plans; and increases in consulting and technology costs of approximately \$431,000 in FY 2023-24; \$791,000 in FY 2024-25; \$1.2 million in FY 2025-26; and \$1.5 million in FY 2026-27; and annually thereafter (Managed Care Fund).
- Costs of an unknown amount to DHCS for Medi-Cal (General Fund, federal funds). CHBRP analyzed a similar bill in 2022, and estimated no additional costs to DHCS, as full-scope Medi-Cal currently provides coverage for biomarker testing as required by this bill.

- The CHBRP analysis noted health plans and insurers currently provide coverage for biomarker testing as required by this bill. However, as new therapies develop, health care expenditures may increase due to increased utilization of high-cost medications. Costs could also be avoided, to the extent that biomarker testing enables safer, more effective interventions. If this bill significantly expands access to biomarker testing, it might increase costs of health coverage, but could also decrease costs if it results in more effective, targeted care.

SUPPORT: (Verified 9/7/23)

American Cancer Society Cancer Action Network (co-source)

University of California (co-source)

Advanced Medical Technology Association

Alliance for Patient Access

American Kidney Fund

Association of Regional Center Agencies

Biocom California

Biogen

Biotechnology Innovation Organization

California Academy of Family Physicians

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 National Medical Center

Crohn's and Colitis Foundation

GSK

International Foundation for Autoimmune and Inflammatory Arthritis

MiOra

Natera

The Latino Cancer Institute

The Michael J. Fox Foundation for Parkinson's Research

OPPOSITION: (Verified 9/7/23)

None received

ARGUMENTS IN SUPPORT: According to the American Cancer Society Cancer Action Network and University of California, co-sponsors 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.

SUPPORT IF AMENDED: The Protection of the Education Rights of Kids has a support if amended position requesting amendments to include protections for information collected, including but not limited to sharing information with third parties or for any other type of use, sharing, of genetic sequencing or medical information detected from the test results.

ASSEMBLY FLOOR: 79-0, 9/13/23

AYES: Addis, Aguiar-Curry, Alanis, Alvarez, Arambula, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Juan Carrillo, Wendy Carrillo, Cervantes, Chen, Connolly, Megan Dahle, Davies, Dixon, Flora, Mike Fong, Vince Fong, Friedman, Gabriel, Gallagher, Garcia, Gipson, Grayson, Haney, Hart, Holden, Hoover, Irwin, Jackson, Jones-Sawyer, Kalra, Lackey, Lee, Low, Lowenthal, Maienschein, Mathis, McCarty, McKinnor, Muratsuchi, Stephanie Nguyen, Ortega, Pacheco, Papan, Jim Patterson, Joe Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Rendon, Reyes, Luz Rivas, Rodriguez, Blanca Rubio, Sanchez, Santiago, Schiavo, Soria, Ta, Ting, Valencia, Villapudua, Waldron, Wallis, Ward, Weber, Wicks, Wilson, Wood, Zbur, Robert Rivas

NO VOTE RECORD: Essayli

Prepared by: Teri Boughton / HEALTH / (916) 651-4111
9/14/23 12:44:47

**** **END** ****