Office of Senate Floor Analyses
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THIRD READING

Bill No: AB 425
Author: Alvarez (D), et al.
Amended: 9/1/23 in Senate
Vote: 21

SENATE HEALTH COMMITTEE: 11-0, 6/28/23
AYES: Eggman, Nguyen, Glazer, Gonzalez, Hurtado, Limón, Menjivar, Roth, Rubio, Wahab, Wiener
NO VOTE RECORDED: Grove

SENATE APPROPRIATIONS COMMITTEE: 7-0, 9/1/23
AYES: Portantino, Jones, Ashby, Bradford, Seyarto, Wahab, Wiener

ASSEMBLY FLOOR: 80-0, 5/31/23 - See last page for vote

SUBJECT: Medi-Cal: pharmacogenomic testing

SOURCE: Invitae Corporation

DIGEST: This bill adds pharmacogenomic testing, as defined, to the Medi-Cal schedule of benefits.

ANALYSIS:

Existing law:

1) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. [WIC §14000, et seq.]

2) Establishes a schedule of benefits under the Medi-Cal program, which includes benefits required under federal law and benefits provided at state option but for which federal financial participation through Medicaid is available. The schedule of benefits includes and Rapid Whole Genome Sequencing for any Medi-Cal beneficiary who is one year of age or younger and is receiving

inpatient hospital services in an intensive care unit and prescription drugs. [WIC §14132]

This bill:

1) Adds pharmacogenomic testing to the Medi-Cal schedule of benefits, subject to utilization controls and evidence based clinical practice guidelines starting July 1, 2024.

2) Defines "pharmacogenomic testing" as laboratory genetic testing that includes, but is not limited to, a panel test to identify how a person's genetics may impact the efficacy, toxicity, and safety of medications.

3) Conditions implementation on the receipt of any necessary federal approvals and the continuation of federal financial participation. Allows DHCS to implement via letter, bulletin, or similar instructions without taking any further regulatory action.

4) States that it is the intent of the Legislature to benefit the total health, including mental and physical health, of Medi-Cal beneficiaries by using available, evidence-based technologies to assess how an individual's genetics impact their metabolism of a variety of medications and to curb the opioid crisis in California, which is exacerbated by genetic changes in individuals that create unintended "high" feelings or no pain relief, prompting increases in opioid dependency. States that through Medi-Cal coverage of pharmacogenomic testing, the safety and efficacy of medications will improve and lead to progress in health equity as well as reduction of adverse drug events, opioid dependency, emergency department visits, and hospital admissions.

Comments

1) *Author's statement.* According to the author, this bill was introduced because a high school student in his District came and shared her story. She had suffered from depression for years, cycling through medications, none of which worked to resolve her symptoms, until finally, she learned of pharmacogenomic testing through a Facebook support group. She thankfully had access to the test and was able to use the results to identify the most effective mental health medication for her. Once she was on the right medication, her symptoms dramatically improved. She recently asserted that pharmacogenomic testing "saved her life" and is now an advocate for ensuring access to the test. This bill would create pharmacogenomic testing access for patients in our Medi-Cal Program. Medi-Cal coverage of pharmacogenomic testing can improve clinical

outcomes for many individuals who are going through mental health and physical health problems.

2) *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 reviewed a similar bill last year, SB 1191 (Bates). Key findings include:

   a) *Benefit coverage.* Based on queries of the Medi-Cal managed care plans, CHBRP found that broadly speaking, all Medi-Cal beneficiaries have coverage for biomarker testing, including pharmacogenomics testing, that is supported by medical and scientific evidence and is determined medically necessary. Pharmacogenomics testing can be performed before a beneficiary begins taking a medication with a companion diagnostic indication (as listed by the FDA), concurrently when a beneficiary is taking a medication with a significant biomarker reference in the FDA drug label, as a panel, or pre-emptively. However, pharmacogenomics testing is not as commonly performed pre-emptively as compared to the other reasons for testing. Because this bill would create clarity of existing benefit coverage, CHBRP concludes that it would, in essence, act as a new benefit coverage mandate. Because the genes relevant to pharmacogenomic testing do not change over time, testing would only need to be completed once and the results would be accessible within a patient's medical records.

   b) *Medical effectiveness.* CHBRP's review of evidence on the effectiveness and clinical utility of pharmacogenomic testing found that it varies significantly across conditions. The majority of literature on the clinical effectiveness and utility of pharmacogenomic testing is condition specific and spans across a wide variety of medical conditions, most notably for cancer and chemotherapy treatments, where pharmacogenomics testing shows particular promise in avoiding adverse reactions to chemotherapy treatment. Other common conditions for which there is literature on pharmacogenomic testing include depression and other psychiatric conditions and cardiovascular disease. Recent clinical trials have shown clinical efficacy for patients with depression in particular. The results on cardiovascular disease have been more mixed with more positive results for testing on a particular drug gene pair as compared to more comprehensive panel testing.

CHBRP found that in a recent analysis of the studies that compared medication changes, a 32% increase in medication changes for patients who had received pharmacogenomic testing was found. A review on hospital admissions found that 11.5% of the patients with pharmacogenomic testing had an unplanned hospital admission as compared to 20.1% of patients who did not have the testing. Another recent study found about 30% of pharmacogenomic testing resulting in recommended changes to optimize therapy. The most common recommendations were to monitor for possible adverse drug reaction or to consider discontinuation of the medication. It is worth noting that while the studies presented show that pharmacogenomic testing may result in recommendations and changes to medication for some patients, especially to prevent adverse reactions, most patients who receive pharmacogenomic testing remain on their previously prescribed medication regimen.

c) *Public health.* Due to a small projected increase in utilization, as well as indeterminate offsets due to other healthcare utilization, CHBRP projects no measurable public health impact at the population level. However, there may be impacts for individuals who receive pharmacogenomics testing with reduced utilization of other health care services such as emergency room visits, unplanned hospital admissions, and outpatient visits. CHBRP did find literature identifying disparities in pharmacogenomic testing by race and ethnicity, socio-economic status, health literacy, and geographic location. Despite an increase in genetic testing in the U.S., non-Hispanic whites have had the most access to such testing, as well as people receiving care at academic medical centers rather than community sites. Again, given the small projected increase in utilization, this bill is not expected to measurably decrease these disparities.

Related/Prior Legislation

SB 1191 (Bates of 2022) also would have added pharmacogenomic testing as a Medi-Cal covered benefit. *SB 1191 was vetoed by Governor Newsom who stated, "I appreciate the author's interest in facilitating access to pharmacogenomic testing, which is currently available in Medi-Cal with prior approval when medically necessary. I have worked with the Legislature to add covered benefits such as continuous glucose monitoring, community health workers, and doula services to the Medi-Cal program through the annual budget process. Although this bill is contingent upon an appropriation, it creates tens of millions of dollars in General Fund cost pressures not accounted for in the budget."*

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

According to the Senate Appropriations Committee, this bill would have unknown, ongoing costs in the Medi-Cal program, likely tens of millions (General Fund and federal funds), due to increased utilization of pharmacogenomic testing.

SUPPORT: (Verified 8/21/23)

Invitae Corporation (source)
Biocom California
California Clinical Laboratories Association
California Life Sciences
California Senior Legislature
California Society of Health System Pharmacists
Color Health, Inc.
Depression and Bipolar Support Alliance California
Helix Op Co, LLC.
Illumina, Inc.
Lab Genomics, LLC.
Northern California Genetic Counselors
Southern California Genetic Counselors
Syngap Research Fund

OPPOSITION: (Verified 8/21/23)

None received

ARGUMENTS IN SUPPORT: Sponsor Invitae, a medical genetics company, writes that there are many studies demonstrating the powerful ability for pharmacogenomic-directed medication management to reduce healthcare costs and improve patient outcomes. One study confirmed that pharmacogenomic testing and pharmacist-guided medication management reduced emergency department visits by 42% and hospitalizations by 52%, saving over $4,300 per patient. Supporters California Life Sciences writes that pharmacogenomic testing allows healthcare providers to precisely tailor therapeutic treatments to patients based on which drugs, biologics, or other medicines are most likely to successfully treat them with the fewest adverse side effects. This improves patient outcomes and saves both time and money for patients, providers, and the healthcare system at large.

ASSEMBLY FLOOR: 80-0, 5/31/23

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, Essayli, 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, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Sanchez, Santiago, Schiavo, Soria, Ta, Ting, Valencia, Villapudua, Waldron, Wallis, Ward, Weber, Wicks, Wilson, Wood, Zbur, Rendon

Prepared by: Jen Flory / HEALTH / (916) 651-4111
9/2/23 9:57:18

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