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

BILL NO: AB 425
AUTHOR: Alvarez
VERSION: March 30, 2023
HEARING DATE: June 28, 2023
CONSULTANT: Jen Flory

SUBJECT: Medi-Cal: pharmacogenomic testing

SUMMARY: Adds pharmacogenomic testing, as defined, as a benefit in the Medi-Cal schedule of benefits.

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. 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, including medications prescribed for behavioral or mental health, oncology, hematology, pain management, infectious disease, urology, reproductive or sexual health, neurology, gastroenterology, or cardiovascular diseases.

2) 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.

FISCAL EFFECT: According to the Assembly Appropriations Committee:

The California Health Benefits Review Program (CHBRP) analysis of a similar bill last year notes that all Medi-Cal beneficiaries have coverage for pharmacogenomic testing that is supported by medical and scientific evidence and is determined medically necessary. CHBRP estimated clarification of existing Medi-Cal coverage policies would lead to an increase in utilization of some pharmacogenomic testing, which would result in an additional 51,900

beneficiaries receiving pharmacogenomic testing if this bill passes -- a 200% increase from the 25,900 beneficiaries who currently receive pharmacogenomic testing. CHBRP estimates costs between $17.6 million and $54.2 million (General Fund and federal funds; likely at least 50% federal), with the possibility of offsetting cost reductions, to the extent use of costlier health services, such as emergency department visits and hospitalizations, are avoided.

CHBRP ran three scenarios based on whether this bill 1) changes utilization only, 2) changes utilization and consolidates billing practices due to multiple single gene tests being billed as a singular panel test, or 3) changes utilization and inflates billing practice due to multiple single gene tests being billed as multiple panel tests. In each scenario modeled, the increase in utilization was the same. However, the billing practices increased cost from $21.7 million in the first scenario, to $17.6 million in the second scenario, to $54.2 million in the last scenario.

CHBRP pointed to several studies that found pharmacogenomic testing could lead to significant cost offsets, including a reduction in emergency room utilization, unplanned hospital admissions, and outpatient visits. The sponsor of this bill, Invitae Corporation, estimates costs of $65 million per year to implement this bill, but also asserts net savings would be $59 million in the first year of implementation and $112 million per year thereafter.

PRIOR VOTES:

Assembly Floor:	80 - 0
Assembly Appropriations Committee:	15 - 0
Assembly Health Committee:	14 - 0

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.

3) *Related legislation.* SB 496 (Limón) requires 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. *SB 496 is set to be heard in the Assembly Health Committee on July 11, 2023.*

4) *Prior legislation.* SB 912 (Limón of 2022) was substantially similar to SB 496. *SB 912 was vetoed by Governor Newsom who stated, "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. . .This bill would establish broad and contradictory coverage requirements that go beyond DHCS's evidence-based policies, which would unnecessarily increase costs without increasing the quality of coverage. I believe the DHCS should retain its current flexibility to establish evidence-based policies in light of the dynamic and changing nature of medicine."*

   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."*

   AB 133 (Committee on Budget, Chapter 143, Statutes of 2021) expanded the Medi-Cal schedule of benefits to include 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.

   AB 114 (Maienschein of 2021) requires rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, to be a covered benefit for any Medi-Cal beneficiary who is one year old or younger and is receiving inpatient hospital services in an intensive care unit. *The contents of AB 114 were included in AB 133.*

   SB 840 (Mitchell, Chapter 29, Statutes of 2018) appropriated $2 million for the rapid Whole Genome Sequencing Pilot Project, known as Project Baby Bear. It required DHCS to provide a grant to a state nonprofit organization for a one-time pilot project to investigate the potential clinical and programmatic value of utilizing rapid Whole Genome Sequencing in the Medi-Cal program.

d) *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.

SUPPORT AND OPPOSITION:

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

Oppose: None received.

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