

Date of Hearing: April 19, 2023

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Chris Holden, Chair

AB 425 (Alvarez) – As Amended March 30, 2023

Policy Committee: Health

Vote: 14 - 0

Urgency: No

State Mandated Local Program: No

Reimbursable: No

**SUMMARY:**

This bill specifies that pharmacogenomic (PGx) testing is a covered benefit under Medi-Cal, subject to utilization controls.

**FISCAL EFFECT:**

The California Health Benefits Review Program (CHBRP) analysis of this bill notes all Medi-Cal beneficiaries have coverage for PGx 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 PGx testing, which would result in an additional 51,900 beneficiaries receiving PGx testing if this bill passes -- a 200% increase from the 25,900 beneficiaries who currently receive PGx 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 PGx 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.

**COMMENTS:**

1) **Purpose.** The author states:

AB 425 was introduced because a high school student in my District came to me 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 (PGx) 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 PGx testing “saved her life” and is now an advocate for ensuring access to the test. I am proud to be the author of this important legislation that would create PGx testing access for patients in our Medi-Cal Program. It’s important to note that having - Cal coverage of PGx testing can improve clinical outcomes for many individuals who are going through mental health and physical health problems.

- 2) **Background.** According to the Centers of Disease Control and Prevention, PGx is an important example of precision medicine, which aims to tailor medical treatment to each person or to a group of people. PGx uses information about a person's genetic makeup, or genome, to choose the drugs and drug doses that are likely to work best for that particular person. According to CHBRP, types of PGx testing include: a) necessary PGx testing for a specific drug (known as a companion diagnostic), b) PGx testing for a specific gene-drug pair but not a required companion diagnostic, c) PGx multigene panel tests to evaluate metabolic response to a medication, and d) preemptive testing using multigene panels across genes-drugs, which can be done before a provider and patient are considering a specific medication, or before considering any medication. Because the genes relevant to PGx testing do not change over time, a patient needs to be tested only once and the results remain accessible within the patient’s medical record.

CHBRP reports the use of PGx in conjunction with a comprehensive medication management program has been shown to help identify medication appropriateness, improve adherence and reduce adverse reactions in a more comprehensive way than either of these approaches can alone. More than 90% of patients are thought to carry at least one genetic variant that should prompt a change in dosing or medication if certain medications are prescribed. Multigene panels allow simultaneous testing of at least two genes, and could include more than 150 genes. PGx testing is performed using a cheek swab or blood sample, which is then sent to a laboratory for analysis.

- 3) **Prior Legislation.** SB 1191 (Bates), of the 2021-22 Legislative Session, also would have added PGx testing as a covered benefit under Medi-Cal. AB 1191 was vetoed by the Governor, who stated:

I appreciate the author's interest in facilitating access to PGx testing, which is currently available in Medi-Cal with prior approval when medically necessary. 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.”

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