AB 425(Alvarez) Medi-Cal: Pharmacogenomic (PGx) Testing

Bill Summary

The COVID-19 pandemic exacerbated the mental health crises, opioid epidemic, and delays in care, leading to patients needing — and taking — more medications than ever. Unfortunately, one-size-fits all prescribing has caused patient harm in those whose genetic makeup is incompatible with the medication they are taking. While some commercial insurances and Medicare cover pharmacogenomic (PGx) testing — the test that determines whether a patient has genetic variations impacting the way their body metabolizes medications — Medi-Cal does not cover the test for its patients.

AB 425 establishes Medi-Cal coverage of PGx panel testing to reduce adverse drug events, improve clinical outcomes, reduce healthcare spend, and create more equitable access to better medication management.

Existing Law

Pharmacogenomic testing has a local coverage determination by Medicare and is covered by many commercial insurances; however, there is currently no explicit coverage by Medi-Cal.

Background

Over 99% of people have one or more genetic variants that impact the way they metabolize medications. A set of several genes contribute to faster, slower, normal, or no metabolism of many medications, resulting in the need for managing their drugs and doses differently to realize the intended effect of the medication (i.e. depression remission or pain relief). Additionally, if people cannot metabolize their medications in the expected way, this may result in a buildup of medication within their bodies, oftentimes resulting in an adverse drug event (ADE). Drug-gene or drug-drug-gene interactions can lead to ADEs that range from side effects to death and are the fourth leading cause of death in the United States. Women and people of color suffer adverse drug events at higher rates than white men, making this issue not only one of clinical effectiveness and safety, but also one of health equity.

A patient can receive a PGx panel test **once** and the information can be used to manage their medications throughout their life. Providing access to this test for patients who are currently taking, or are being prescribed, a medication included in CPIC guidelines or the FDA's published table may result in medication changes. Medication management informed by pharmacogenomics can result in more effective prescribing, with a patient's unique genetic makeup being a source of information for prescribers and pharmacists. In fact, based on studies projecting reductions in emergency visits and hospitalizations, this bill should result in net savings of $59.1M, after the cost of testing.[1] In a recent real-world study on PGx implementation and pharmacist-guided medication management, 66% of patients were found to have a genetic variant impacting current medications and a cost savings of $32M was realized over 32 months.[2]

[1] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0170905

[2] https://www.thejournalofprecisionmedicine.com/real-world-impact-of-pharmacogenomics-and-comprehensive-medication-management-revealed-in-new-coriell-life-sciences-case-study/

Details of the Bill

Medi-Cal coverage of PGx testing will mitigate health inequities and improve quality of care while reducing costs by providing pharmacogenomic information that ensures patients are receiving the appropriate dose of the correct medicine. If enacted, AB 425 would:

- Provide coverage to Medi-Cal patients who are prescribed, or who are already taking, medications with identified evidence-based pharmacogenomic interactions (CPIC or FDA).
- Allow flexibility in the setting for collection of the specimen (e.g. at-home, pharmacy, or health facility)
- Assure PGx tests are high quality by requiring the laboratory to be CA-licensed and accredited by a CMS-approved accreditation body
- Ensure the PGx test is affordable
- Ensure access to the test is not hindered by prior authorization processes

Support

- Invitae (Sponsor)

For More Information

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