ASSEMBLY THIRD READING
AB 425 (Alvarez)
As Amended March 30, 2023
Majority vote

SUMMARY

Specifies that pharmacogenomic testing, as defined, is a covered benefit under Medi-Cal, subject to utilization controls.

COMMENTS

1) *Pharmacogenomics.* According to the Centers of Disease Control and Prevention (CDC), pharmacogenomics is an important example of the field of precision medicine, which aims to tailor medical treatment to each person or to a group of people. According to the National Human Genome Research Institute (Institute) under the federal National Institutes of Health, pharmacogenomics 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. This field combines the science of how drugs work, called pharmacology, with the science of the human genome, called genomics.

   Pharmacogenomic testing is performed using a cheek swab or blood sample, which is then sent to a laboratory for analysis. The CDC indicates doctors are starting to use pharmacogenomic information to prescribe drugs, but such tests are routine for only a few health problems, including certain cancers. For instance, someone with a particular genetic makeup may have an adverse reaction to a certain treatment. However, given the field's rapid growth, pharmacogenomics is soon expected to lead to better ways of using drugs to manage heart disease, cancer, asthma, depression and many other common diseases.

   Invitae Corporation, the sponsor of this bill, points out improving coverage of pharmacogenomics is important to improve health equity, given women and people of color are more likely to experience negative outcomes and adverse drug events resulting from a medication they take. Due to historical practices that excluded women and people of color from clinical trials, Invitae notes, many of the recommended doses and medications are predicated on evidence generated by studies involving primarily non-Hispanic white men. For this reason, Invitae asserts improving coverage for pharmacogenomics testing that can help optimize medication will have a disproportionate positive impact on women and people of color.

2) *California Health Benefits Review Program (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. CHBRP reviewed similar bill last year, SB 1191 (Bates) of 2022. Components of the SB 1191 analysis relevant to this bill include the following**:**

   a) *Impact on Medi-Cal expenditures.* Several studies that found pharmacogenomics testing could lead to significant cost offsets, including a reduction in emergency room utilization, unplanned hospital admissions, and outpatient visits, but CHBRP could not make a

projection of actual savings. There is some evidence that the use of pharmacogenomic testing for specific types of diseases is cost-effective, but this varies significantly by disease, treatment, and outcomes assessed.

b) Medical effectiveness.

i) The use of pharmacogenomics 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.

ii) Evidence on the effectiveness and clinical utility of pharmacogenomic testing varies significantly across conditions. Some studies have found that pharmacogenomic testing leads to changes in medications and a reduction in hospital admissions. While the studies identified by CHBRP show that pharmacogenomic testing may result in changes to medication for some patients, especially to prevent adverse reactions, most patients who receive pharmacogenomic testing remain on their previously prescribed medication regimen

CHBRP also notes systematic reviews of the efficacy of pharmacogenomics testing have described the weakness of relevant literature as having insufficient sensitivity analyses, heterogeneity in study designs and populations, and low quality of data and methodologies.

3) *Current Medi-Cal Coverage.* According to the CHBRP analysis of SB 1191, 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. However, Medi-Cal coverage of pharmacogenomic testing is not clearly specified. Based on a search of the Medi-Cal provider manual, the only reference to pharmacogenomic testing is CPT code 81418 (described as "Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least six genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis"), which is listed in the Medi-Cal provider manual as a non-benefit. Some other genetic tests the author provided as commonly used for pharmacogenomics purposes are also not listed in the Medi-Cal provider manual, are listed as non-benefits, or are listed as covered with an approved treatment authorization request (TAR).

However, in spite of the status of some pharmacogenomics-related services codes as non-benefits, they can be covered by Medi-Cal if specified conditions are met. The Medi-Cal provider manual specifies Medi-Cal may provide reimbursement for a non-benefit with an approved TAR if medical necessity is established. This bill is intended to clarify Medi-Cal coverage for pharmacogenomic testing and clearly specify the parameters of coverage.

According to the Author
Having Medi-Cal coverage of pharmacogenomic testing can improve clinical outcomes for many individuals who are going through mental health and physical health problems. As an example, the author indicates a high school student in the author's district suffered from depression for years, cycling through medications, none of which worked to resolve the student's symptoms. The student finally learned of pharmacogenomic testing through a Facebook support group. The

author explained the student gained access to the test and was able to use the results to identify the most effective mental health medication for the student, and the student's symptoms dramatically improved with the right medication.

Arguments in Support
Invitae Corporation, this bill's sponsor, indicates several commercial insurances cover pharmacogenomic testing for their beneficiaries, and this bill will mitigate those disparities and open up access to this potentially life-saving test. Biocom, in support, states this bill will reduce adverse drug events, improve clinical outcomes, reduce healthcare spending, and create more equitable access to better medication management.

Arguments in Opposition
There is no known opposition.

FISCAL COMMENTS

According to the Assembly Appropriations Committee:

The CHBRP analysis of this bill notes 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.

VOTES

ASM HEALTH: 14-0-1
YES: Wood, Waldron, Aguiar-Curry, Arambula, Boerner Horvath, Flora, Vince Fong, Maienschein, McCarty, Joe Patterson, Rodriguez, Santiago, Villapudua, Weber
ABS, ABST OR NV: Wendy Carrillo

ASM APPROPRIATIONS: 15-0-1

YES: Holden, Megan Dahle, Bryan, Calderon, Wendy Carrillo, Dixon, Mike Fong, Hart, Lowenthal, Mathis, Papan, Pellerin, Sanchez, Weber, Ortega
ABS, ABST OR NV: Robert Rivas

UPDATED

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CONSULTANT: Lisa Murawski / HEALTH / (916) 319-2097 FN: 0000699