CONCURRENCE IN SENATE AMENDMENTS
AB 425 (Alvarez)
As Amended September 1, 2023
Majority vote

SUMMARY

Specifies that pharmacogenomic testing, as defined, is a covered benefit under Medi-Cal, subject to utilization controls and evidence-based clinical practice guidelines.

Senate Amendments

1) Condition implementation on federal approvals have been obtained and federal financial participation is available and not otherwise jeopardized.

2) Strike provisions that specified a range of health conditions for which pharmacogenomics testing can be used.

3) Authorize the Department of Health Care Services to implement the bill's provisions through bulletins or similar non-regulatory instructions.

4) Clarify coverage is based on evidence-based clinical practice guidelines (in addition 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 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 that 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.* CHBRP, an analytical team housed in the University of California with a statutory charge to review legislative benefit mandates, analyzed the impact of this bill. CHBRP reviewed a 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. However, 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. In addition, 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 Treatment Authorization Request (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 insurance plans cover pharmacogenomic testing for their beneficiaries, and this bill will mitigate disparities between those covered by public and commercial coverage, as well as 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 Senate Appropriations Committee, unknown, ongoing costs in the Medi-Cal program, likely tens of millions (General Fund and federal funds), due to increased utilization of pharmacogenomic testing.

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

ASSEMBLY FLOOR: 80-0-0
YES: 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

SENATE FLOOR: 39-0-1
YES: Allen, Alvarado-Gil, Archuleta, Ashby, Atkins, Becker, Blakespear, Bradford, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez, Grove, Hurtado, Jones, Laird, Limón,

McGuire, Menjivar, Min, Newman, Nguyen, Niello, Ochoa Bogh, Padilla, Portantino, Roth, Rubio, Seyarto, Skinner, Smallwood-Cuevas, Stern, Umberg, Wahab, Wiener, Wilk
ABS, ABST OR NV: Caballero

UPDATED

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