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| BILL ANALYSIS |

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| S.B. 989 |
| By: Huffman |
| Insurance |
| Committee Report (Unamended) |

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| **BACKGROUND AND PURPOSE** Biomarker testing is a feature of precision medicine that allows doctors to use information abouta person's specific genetic variations to inform better diagnosis, prognosis, and therapy selectionfor cancer or rare disease patients. Currently, health insurance coverage of biomarker testing is not an across-the-board guarantee, nor is it being consistently reimbursed by the health plans in Texas. S.B. 989 seeks to require a health benefit plan to provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment when the test is supported by certain kinds of medical and scientific evidence.  |
| **CRIMINAL JUSTICE IMPACT**It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision. |
| **RULEMAKING AUTHORITY** It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution. |
| **ANALYSIS** S.B. 989 amends the Insurance Code to require a health benefit plan to provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment when the test is supported by the following kinds of medical and scientific evidence:* a labeled indication for a test approved or cleared by FDA;
* an indicated test for a drug approved by FDA;
* a national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare administrative contractor;
* nationally recognized clinical practice guidelines; or
* consensus statements.

A health benefit plan issuer is required to provide such coverage only when use of biomarker testing provides clinical utility because use of the test for the condition is evidence-based, scientifically valid based on the medical and scientific evidence, informs a patient's outcome and a provider's clinical decision, and predominately addresses the acute or chronic issue for which the test is being ordered, except that a test may include some information that cannot be immediately used in the formulation of a clinical decision. A health benefit plan must provide that coverage in a manner that limits disruptions in care, including limiting the number of biopsies and biospecimen samples. S.B. 989 defines the following terms:* "biomarker" as a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including gene mutations and protein expression;
* "biomarker testing" as the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker, including single-analyte tests, multiplex panel tests, and whole genome sequencing;
* "consensus statements" as statements that address specific clinical circumstances based on the best available evidence for the purpose of optimizing clinical care outcomes and are developed by an independent, multidisciplinary panel of experts that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy; and
* "nationally recognized clinical practice guidelines" as evidence-based clinical practice guidelines that establish a standard of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options, include recommendations intended to optimize patient care, and are developed by an independent organization or medical professional society that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy.

S.B. 989 specifies the types of plans and sources of coverage to which its provisions apply. The bill provides for the delayed implementation of any provision for which an applicable state agency determines a federal waiver or authorization is necessary for implementation until the waiver or authorization is requested and granted. The bill's provisions apply only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2024. |
| **EFFECTIVE DATE** September 1, 2023. |