

SENATE BILL REPORT

SB 5822

As of January 26, 2022

Title: An act relating to insurance coverage for biomarker testing.

Brief Description: Concerning insurance coverage for biomarker testing.

Sponsors: Senators Wilson, L., Brown, Dozier, Frockt, Hasegawa, Stanford and Warnick.

Brief History:

Committee Activity: Health & Long Term Care: 1/28/22.

Brief Summary of Bill

- Requires insurance coverage for biomarker testing when supported by medical and scientific evidence.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Greg Attanasio (786-7410)

Background: The United States Food and Drug Administration (FDA) defines a biomarker as a characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. According to the National Institutes of Health, a biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease, which may be used to see how well the body responds to a treatment for a disease or condition. Biomarker testing has been used in a number of clinical applications, including screening and diagnostic tests, treatment and post-treatment monitoring, prognostic tests for estimating risk or time to clinical outcomes, and to predict patient response to specific treatments.

Summary of Bill: Beginning January 1, 2023, health carriers, nonprofit health benefit plans, and health maintenance organizations must provide coverage for biomarker

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testing for the diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including:

- labeled indications for tests approved by the FDA or indicated tests for a drug approved by the FDA;
- Centers for Medicare and Medicaid Services national coverage determinations; or
- nationally recognized clinical practice guidelines.

Carriers must ensure coverage is provided in a manner that limits disruptions in care, including limiting the need for multiple biopsies or biospecimen samples.

"Biomarker" means 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. Biomarkers include, but are not limited to, gene mutations or protein expression.

"Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.

Appropriation: None.

Fiscal Note: Requested on January 25, 2022.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.