

SENATE BILL REPORT

SB 5074

As of January 18, 2023

Title: An act relating to coverage for biomarker testing.

Brief Description: Concerning coverage for biomarker testing.

Sponsors: Senators Wilson, L., Cleveland, Braun, Dozier, Fortunato, Van De Wege and Warnick.

Brief History:

Committee Activity: Health & Long Term Care: 1/20/23.

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 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, 2024, health plans, including plans offered to

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public employees, and Medicaid must include coverage for biomarker 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;
- nationally recognized clinical practice guidelines; or
- consensus statements developed by an independent, multidisciplinary panel of experts aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

Coverage must be provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

Appropriation: None.

Fiscal Note: Requested on January 10, 2023.

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

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