HOUSE BILL REPORT
HB 1450

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to coverage for biomarker testing.

Brief Description: Concerning coverage for biomarker testing.

Sponsors: Representatives Stonier, Harris, Simmons, Reed and Macri.

Brief History:
Committee Activity:
Health Care & Wellness: 1/31/23, 2/8/23 [DPS], 1/26/24, 1/30/24 [DP2S].

Brief Summary of Second Substitute Bill

- Requires health plans, including plans offered to public and school employees and Medicaid, to provide coverage for biomarker testing when supported by medical and scientific evidence.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The second substitute bill be substituted therefor and the second substitute bill do pass. Signed by 17 members: Representatives Riccelli, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Hutchins, Assistant Ranking Minority Member; Bronoske, Caldier, Davis, Graham, Harris, Macri, Maycumber, Mosbrucker, Orwall, Simmons, Stonier, Thai and Tharinger.

Staff: Kim Weidenaar (786-7120).

Background:

According to the United States Food and Drug Administration (FDA), a biomarker is a defined characteristic that is measured as an indicator of normal biological processes,

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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 posttreatment monitoring, prognostic tests for estimating risk or time to clinical outcomes, and to predict patient response to specific treatments.

Summary of Bill (Second Substitute):

Health plans, including plans offered to public employees, issued or renewed on or after January 1, 2025, and Medical Assistance Programs (Medicaid) must include coverage for biomarker testing. Biomarker testing must be covered for diagnosis, treatment, appropriate management, or ongoing monitoring of the enrollee's disease or condition if the test is supported by medical and scientific evidence including:

- labeled indications for tests approved or cleared by the FDA or indicated tests for a drug approved by the FDA;
- Centers for Medicare and Medicaid Services coverage determinations or Medicare administrative contractor coverage determinations; or
- nationally recognized clinical practice guidelines developed by independent organizations or medical professional societies that establish standards of care informed by a systematic review of evidence, and an assessment of the benefits and costs of alternative care options.

Health carriers, health plans offered to public employees, and the Health Care Authority (HCA) must ensure this coverage is provided in a manner that limits the need for multiple biopsies or samples. Biomarker screening tests and biomarker testing that is investigatory in nature are not required to be covered. To the extent otherwise allowed and not prohibited by these requirements, health plans may apply prior authorization and utilization management strategies to biomarker testing. The HCA must also seek any available federal Medicaid financial participation and any other federal funding sources.

"Biomarker" is defined 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 and includes 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, including single-analyte tests, multiplex panel tests, and whole genome sequencing.

Second Substitute Bill Compared to Original Bill:

The second substitute bill:

- removes consensus statements from the types of medical and scientific evidence that support the use of biomarker testing for this purpose;
- specifies that biomarker screening tests and biomarker testing that is investigatory in nature are not required to be covered;
- specifies that to the extent allowed under the relevant regulatory chapter for the type of health plan and not prohibited by the bill's requirements, health plans may apply prior authorization and utilization management strategies to biomarker testing;
- modifies the provision that requires health plans to ensure coverage for biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples by removing the reference to disruptions in care; and
- applies to health plans issued or renewed on or after January 1, 2025, instead of January 1, 2024.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on January 30, 2024.

Effective Date of Second Substitute Bill: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) Last year the discussion around this bill was narrowed to just cancer as it is one of the areas where biomarker testing can have a significant impact. However, over the interim, there were discussions of the many other types of conditions that can benefit from biomarker testing, including preeclampsia. Preeclampsia is a very high-risk condition and comes with very high costs. There are concerns about the cost to plans and it is why the bill was narrowed last year. However, biomarker testing is a more strategic treatment, and we should be taking advantage of new technologies.

Biomarker testing is the standard of care for many cancers and other conditions. Biomarker testing guides doctors to the best targeted treatments. Fourteen other states have passed this model legislation and these states are not seeing the high predicted cost increases to the same extent.

As precision therapy becomes the standard of care, biomarker testing is no longer optional. Fifty-five percent of plans do not cover biomarker testing in ways that are supported by the standard of care.

When biomarker testing is utilized, health care providers do not waste time, energy, and money on therapies that do not work. Contemporary medicine is on the cusp of personalized and precision medicine due to biomarker testing. When biomarker testing is

used to figure out the subtype of the cancer, this provides more information on what might work for the patient, which sometimes allows the patient to avoid chemotherapy which causes lots of toxicity.

The United States is the only developed country in the world where maternal death rates are increasing, and preeclampsia is the leading cause of those deaths. Eighty-four percent of those deaths were preventable according to the federal Centers for Disease Control and Prevention. A biomarker test for preeclampsia was approved in May of 2023 and there is a lot of research in this area currently. The test allows for the provision of appropriate care.

As with many diseases, early detection and treatment is crucial for changing the trajectory of amyotrophic lateral sclerosis (ALS) and preventing severe illness and complications. Biomarker testing allows more people to get lifesaving early warning signs of ALS and reduce the long-term burden with early diagnosis. Early diagnosis is essential for managing ALS and individuals can go a year after the onset of symptoms before receiving a diagnosis.

Biomarker testing is needed in order to use precision therapies, but insurance often will not cover these tests, so the patients either have to pay high out-of-pocket costs or appeal the decision and delay their care. Not everyone can afford to do that.

Biomarker testing is vital to ensure all Washingtonians have access to the best treatments available. Individualized care is leading to the best outcomes. Often clinical trials may provide the best chance, but you can only qualify for trials after biomarker testing.

(Opposed) The fiscal note shows that both the original bill and substitute likely will have a substantial impact on cost. The impact of this bill on health premiums should be considered. The health plans moderated their position last year based on narrowing of the bill in the substitute. This bill includes investigative treatments.

(Other) The Office of the Insurance Commissioner (OIC) reviewed the potential impacts of adding biomarkers to the state's essential health benefits benchmark plan. In the report submitted on December 31, the OIC concluded that biomarker testing is currently included in the essential health benefits when the testing meets medical necessity standards and so it is not a new mandate. The issue here is the medical necessity criteria applied by health carriers.

Persons Testifying: (In support) Representative Monica Jurado Stonier, prime sponsor; Matthew Helder, American Cancer Society Cancer Action Network; Katie Kolan and Blair Irwin, Washington State Medical Oncology Society; Allanda Christenson; Kara Boeldt, EndPreeclampsia; Clark Hansen, Amyotrophic Lateral Sclerosis Association; Thomas McElrath, Harvard School of Medicine; and Cameron Long, Genentech.

(Opposed) Jennifer Ziegler, Association of Washington Health Care Plans.

(Other) Delika Steele, Office of the Insurance Commissioner.

Persons Signed In To Testify But Not Testifying: Valerie Daggett, AltPep.