

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].

Brief Summary of Substitute Bill

- Requires health insurance coverage for biomarker testing for the diagnosis, treatment, appropriate management, or ongoing monitoring of stage 1, 2, 3, or 4 cancer and brain cancer.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 15 members: Representatives Riccelli, Chair; Bateman, Vice Chair; Hutchins, Assistant Ranking Minority Member; Barnard, Bronoske, Davis, Graham, Harris, Macri, Maycumber, Mosbrucker, Simmons, Stonier, Thai and Tharinger.

Minority Report: Do not pass. Signed by 1 member: Representative Schmick, Ranking Minority Member.

Staff: Kim Weidenaar (786-7120).

Background:

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

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, 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.

In 2022 legislation was enacted to require health plans issued or renewed on or after January 1, 2023, to exempt an enrollee from prior authorization requirements for coverage of biomarker testing for either stage 3 or 4 cancer; or recurrent, relapsed, refractory, or metastatic cancer. The biomarker testing must be:

- recommended in the latest version of nationally recognized guidelines or biomarker compendia;
- approved by the FDA or a validated clinical laboratory test performed in a clinical laboratory certified under the Clinical Laboratory Improvement Amendments or in an alternative laboratory program approved by the Centers for Medicare and Medicaid Services;
- a covered service; and
- prescribed by an in-network provider.

A health plan is not prohibited from requiring a biomarker test prior to approving a drug or treatment and an enrollee's right to access individual gene tests is not limited.

Summary of Substitute Bill:

Health plans, including plans offered to public employees, issued or renewed on or after January 1, 2024, and medical assistance programs (Medicaid) must include coverage for biomarker testing for stage 1, 2, 3, or 4 cancer and brain cancer. Biomarker testing must be covered for diagnosis, treatment, appropriate management, or ongoing monitoring of the enrollee's stage 1, 2, 3, or 4 cancer or brain cancer if the test is supported by medical and scientific evidence including:

- labeled indications for tests approved by the United States Food and Drug Administration (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;
- 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; or

- consensus statements developed by an independent, multidisciplinary panel of experts aimed at specific clinical circumstances and based on the best available evidence.

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 disruptions of care including the need for multiple biopsies or samples. 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.

Substitute Bill Compared to Original Bill:

The substitute bill limits the requirement to provide coverage for biomarker testing to only the diagnosis, treatment, appropriate management, or ongoing monitoring of stage 1, 2, 3, or 4 cancer or brain cancer.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on February 9, 2023.

Effective Date of 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) Biomarker testing is no longer just nice to have in oncology, it is the standard of care in cancer treatment. Some states have already passed similar requirements. Arizona passed a bill unanimously and the fiscal note was only \$450,000 and the per member per month cost was 14 to 51 cents. This bill saves money in the end and the average savings is \$8,500 when patients had access to biomarker testing. There is a huge gap in Washington; 55 percent of covered lives in Washington have plans that do not cover biomarkers in line with clinical guidelines.

Without biomarker testing some people would not be alive today. Biomarker testing helps health care providers know how aggressive a cancer is, how likely it is to spread, what the best treatments are for the specific cancer, and the patient's prognosis. These tests allow a provider to understand the unique biology of the cancer. It is essential for designing a treatment plan, allows patients to have the correct treatments, and sometimes helps patients

avoid the pain of chemotherapy. In addition to helping find the right treatments, biomarker testing can also exclude certain treatments, which saves money. Time is of the essence for people with cancer and biomarker testing can change the trajectory for these patients.

Biomarker testing is no long optional in oncology. The law has not kept up with the science in this area. Biomarker testing allows the best science to be applied to cancer and there has never been a better time to have cancer. However, this is not true for those who do not have access to this testing. Everyone should have an equal shot of survival regardless of the insurance card that they carry.

(Opposed) A number of plans cover a broad range of biomarker testing. All of the testimony on the bill has focused on cancer, but this bill is not limited to cancer. This bill is not the only insurance mandate that the Legislature is considering and they all have an impact on costs. Insurance coverage should strike a balance between the quality of care and the cost of care, but this legislation does not strike this balance.

Persons Testifying: (In support) Representative Monica Jurado Stonier, prime sponsor; Eric Konnick; Matt Helder, American Cancer Society Cancer Action Network; Robin Sparks; Katie Kolan, Washington State Medical Oncology Society; Jay Lopez, Swedish Cancer Institute; Kristina Stolte; and Osta Davis.

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

Persons Signed In To Testify But Not Testifying: None.