FINAL BILL REPORT
ESHB 1689

C 123 L 22
Synopsis as Enacted

Brief Description: Exempting biomarker testing from prior authorization for patients with late stage cancer.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Walen, Harris, Leavitt, Graham, Duerr, Davis, Slatter and Tharinger).

House Committee on Health Care & Wellness
Senate Committee on Health & Long Term Care

Background:

Biomarkers.
According to the United States Food and Drug Administration, 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 is 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.

Clinical Laboratory Improvement Amendments.
The Centers for Medicare and Medicaid Services regulates all laboratory tests on human specimens through the Clinical Laboratory Improvement Amendments (CLIA) except for research. Clinical laboratories must be CLIA certified to receive reimbursement from Medicare or Medicaid.

Prior Authorization.
Prior authorization is the requirement that a provider receive approval from a health carrier

---

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.

prior to performing a health care service for reimbursement.

Summary:

Health plans issued or renewed on or after January 1, 2023, must exempt an enrollee from prior authorization requirements for coverage of biomarker testing for either of the following:

- 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 United States Food and Drug Administration 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.

For purposes of these requirements, a biomarker test is a single or multigene diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA, RNA, or protein alternations, including phenotypic characteristics of malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment.

Votes on Final Passage:

House	95	0	
Senate	48	0	(Senate amended)
House	97	1	(House concurred)

Effective: June 9, 2022