Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1689

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

Sponsors: Representatives Walen, Harris, Leavitt, Graham, Duerr, Davis, Slatter and Tharinger.

Brief Summary of Bill

- Requires health plans to exempt biomarker testing for cancer or cancer progression or recurrence from prior authorization requirements.

Hearing Date: 1/13/22

Staff: Kim Weidenaar (786-7120).

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 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.

Clinical Laboratory Improvement Amendments.

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.

The Centers for Medicare and Medicaid Services regulates all laboratory tests on human specimens through the Clinical Laboratory Improvement Amendments (CLIA) except for research. The purpose of CLIA is to ensure labs provide accurate, reliable, and timely patient test results. 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 prior to performing a health care service for reimbursement.

Summary of Bill:

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

- stage 1, 2, 3, or 4 cancer; or
- cancer progression or recurrence in the enrollee with stage 1, 2, 3, or 4 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.

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.

Appropriation: None.

Fiscal Note: Available.

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