HOUSE BILL REPORT
ESHB 1689

As Passed Legislature

Title: An act relating to exempting biomarker testing from prior authorization for patients with late stage cancer.

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).

Brief History:

Committee Activity:

Health Care & Wellness: 1/13/22, 1/26/22 [DPS].

Floor Activity:

Passed House: 2/8/22, 95-0.
Senate Amended.
Passed Senate: 3/4/22, 48-0.
House Concurred.
Passed House: 3/7/22, 97-1.
Passed Legislature.

Brief Summary of Engrossed Substitute Bill

- Requires health plans to exempt enrollees from prior authorization requirements for biomarker testing for stage 3 or 4 cancer or recurrent, relapsed, refractory, or metastatic 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 Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Bronoske, Davis,

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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.

Harris, Macri, Maycumber, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

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.
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 Engrossed Substitute Bill:

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.

The provisions do not prohibit a health plan from requiring a biomarker test prior to approving a drug or treatment and does not limit an enrollee's right to access individual gene tests.

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.

Staff Summary of Public Testimony:

(In support) Big decisions must be made when you have cancer and often the worst part is the waiting. You have to wait for results, wait and see if treatment is working, and wait and see if anything has come back. There are also delays at every stage. First you need prior authorization for the biomarker test and then again for the treatment. Eliminating the delay for late state or any stage cancer, gets patients to treatment faster. This bill is targeted towards people that do not have the luxury of time and anything that restricts access or creates delays in testing is not good for patients. Timely access to biomarker testing at diagnosis and progression saves lives and allows for patients to be put on the most appropriate and successful treatments. Prior authorization can cause harmful delays and can sometimes result in the denial of lifesaving treatment.

This bill is narrowly tailored and is not a benefit mandate. Biomarker testing for a number of cancers is already the standard of care and so prior authorization is not appropriate. For example, prior authorization requests for lung cancer are almost always approved.

While this bill is still a work in progress and is not perfect, it should not wait. This is a lifesaving bill, and passing this bill is something that should be done today.

(Opposed) Access to biomarker testing is critical, but this bill falls short because it does not address insurance coverage of the testing. Most oncologists say that coverage of biomarker testing, rather than prior authorization requirements, is the biggest obstacle to this care. Accordingly, this bill does not address existing disparities and instead exacerbates them by only focusing on those who already have coverage for biomarker testing.

Some blood and brain cancers are not staged and so are excluded from the bill. Other states, like Illinois and Louisiana, have bills that would better address the concerns. There is also some concern that this bill only applies to individual biomarker tests and most of the biomarker tests are part of a larger panel.

(Other) Prior authorization is used to make sure that people do not get surprised with bills later on if the insurer determines that the service was not medically necessary.

The biggest remaining issue is on the scope of the bill. Existing clinical evidence does not support the application of biomarker testing for all types of cancer and at all stages. It does not make sense to list specific types of cancer in statute, and so some are searching for a way forward to narrow this bill's application. The federal Centers for Medicare and Medicaid Services uses an approach for Medicare that relates to the clinical type of cancer and medical necessity and may be an option for this bill.

Persons Testifying: (In support) Representative Amy Walen, prime sponsor; and Kristen Santiago, LUNGevity Foundation.

(Opposed) Matt Helder, American Cancer Society Cancer Action Network; and Katie Kolan, Washington State Medical Oncology Society.

(Other) Chris Bandoli, Association of Washington Healthcare Plans.

Persons Signed In To Testify But Not Testifying: None.