SENATE BILL REPORT
ESHB 1689

As of February 21, 2022

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: Passed House: 2/8/22, 95-0.
Committee Activity: Health & Long Term Care: 2/21/22.

Brief Summary of Bill

- Requires health plans and Medicaid managed care plans to exempt enrollees from prior authorization requirements for biomarker testing for stage 3 or 4 cancer or recurrent, relapsed, refractory, or metastatic cancer.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Greg Attanasio (786-7410)

Background: Biomarkers. 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,

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treatment and post-treatment 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.

Summary of Bill: Health plans issued or renewed on or after January 1, 2023, and Managed Care Organizations for Medicaid managed care plans upon initiation or renewal of a contract with the Health Care Authority, 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 FDA or a validated clinical laboratory test performed in a clinical laboratory certified under the CLIA 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 or managed care 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. New fiscal note requested on February 16, 2022.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: This policy is linked to national standards of cancer care. Time is of the essence when it relates to late stage cancer and delays for prior

authorization also delay treatment decisions. Biomarker testing is a critical piece of cancer care to determine what treatments are appropriate.

OTHER: Health plans do not have objection to the current form of the bill and the bill should not further change.

CON: The bill should address coverage for biomarker testing and no only prior authorization. This will only help a small subset of patients, and existing inequities will grow.

Persons Testifying: PRO: Representative Amy Walen, Prime Sponsor; Sara Grethlein, MD, Swedish Medical Group; Nikki Martin, Director of Precision Medicine, Lungevity Foundation.

CON: Matt Helder, American Cancer Society Cancer Action Network.

OTHER: Chris Bandoli, Association of WA Healthcare Plans.

Persons Signed In To Testify But Not Testifying: No one.