Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1450

Brief Description: Concerning coverage for biomarker testing.

Sponsors: Representatives Stonier, Harris, Simmons, Reed and Macri.

Brief Summary of Bill

- Requires health plans, including plans offered to public and school employees and Medicaid, to provide coverage for biomarker testing when supported by medical and scientific evidence.

Hearing Date: 1/26/24

Staff: Kim Weidenaar (786-7120).

Background:

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.

Summary of Bill:

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.

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. Biomarker testing must be covered for diagnosis, treatment, appropriate management, or ongoing monitoring of the enrollee's disease or condition if the test is supported by medical and scientific evidence including:

- labeled indications for tests approved or cleared by the 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.

Appropriation: None.

Fiscal Note: Available.

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