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**SENATE BILL 5822**

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**State of Washington 67th Legislature 2022 Regular Session**

**By** Senators L. Wilson, Brown, Dozier, Frockt, Hasegawa, Stanford, and Warnick

AN ACT Relating to insurance coverage for biomarker testing; and adding a new section to chapter 48.43 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec.**  A new section is added to chapter 48.43 RCW to read as follows:

(1) Health insurers, nonprofit health benefit plans, and health maintenance organizations issuing, amending, delivering, or renewing a health insurance contract on or after January 1, 2023, shall include coverage for biomarker testing, pursuant to the criteria established under subsection (2) of this section.

(2) Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence including, but not limited to:

(a) Labeled indications for tests approved or cleared by the United States food and drug administration or indicated tests for a drug approved by the United States food and drug administration;

(b) Centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(c) Nationally recognized clinical practice guidelines and consensus statements.

(3) Health insurers, nonprofit health benefit plans, and health maintenance organizations shall ensure coverage as defined in subsection (2) of this section is provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The patient and prescribing practitioner shall have access to clear, readily accessible, and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit health benefit plan, and health maintenance organization. The process shall be made readily accessible on the health insurer's, nonprofit health benefit plan's, or health maintenance organization's website.

(5) For the purposes of this section:

(a) "Biomarker" means 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. Biomarkers include but are not limited to gene mutations or protein expression.

(b) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests, multiplex panel tests, and whole genome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

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