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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

Read first time 01/12/22. Referred to Committee on Health & Long Term Care.

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

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

4 NEW SECTION. **Sec. 1.** A new section is added to chapter 48.43  
5 RCW to read as follows:

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

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

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

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

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

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

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

14 (5) For the purposes of this section:

15 (a) "Biomarker" means a characteristic that is objectively  
16 measured and evaluated as an indicator of normal biological  
17 processes, pathogenic processes, or pharmacologic responses to a  
18 specific therapeutic intervention. Biomarkers include but are not  
19 limited to gene mutations or protein expression.

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

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

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

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