
SENATE BILL 5822

State of Washington

67th Legislature

2022 Regular Session

By Senator L. Wilson

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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