
SENATE BILL 5074

State of Washington

68th Legislature

2023 Regular Session

By Senators L. Wilson, Cleveland, Braun, Dozier, Fortunato, Van De Wege, and Warnick

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1 AN ACT Relating to coverage for biomarker testing; adding a new
2 section to chapter 48.43 RCW; adding a new section to chapter 41.05
3 RCW; and adding a new section to chapter 74.09 RCW.

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

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

7 (1) For health plans issued or renewed on or after January 1,
8 2024, a health carrier shall include coverage for biomarker testing
9 pursuant to the criteria established under subsection (2) of this
10 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 or medicare administrative contractor local coverage
20 determinations;

21 (c) Nationally recognized clinical practice guidelines; or

1 (d) Consensus statements.

2 (3) Health carriers shall ensure coverage as required in
3 subsection (2) of this section is provided in a manner that limits
4 disruptions in care including the need for multiple biopsies or
5 biospecimen samples.

6 (4) For the purposes of this section:

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

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

16 (c) "Consensus statements" means statements that are:

17 (i) Developed by an independent, multidisciplinary panel of
18 experts utilizing a transparent methodology and reporting structure
19 and with a conflict of interest policy;

20 (ii) Aimed at specific clinical circumstances; and

21 (iii) Based on the best available evidence for the purpose of
22 optimizing the outcomes of clinical care.

23 (d) "Nationally recognized clinical practice guidelines" means
24 evidence-based clinical practice guidelines that:

25 (i) Are developed by independent organizations or medical
26 professional societies utilizing a transparent methodology and
27 reporting structure and with a conflict of interest policy;

28 (ii) Establish standards of care informed by a systematic review
29 of evidence and an assessment of the benefits and costs of
30 alternative care options; and

31 (iii) Include recommendations intended to optimize patient care.

32 NEW SECTION. **Sec. 2.** A new section is added to chapter 41.05
33 RCW to read as follows:

34 (1) A health plan offered to public employees and their covered
35 dependents under this chapter issued or renewed on or after January
36 1, 2024, shall include coverage for biomarker testing pursuant to the
37 criteria established under subsection (2) of this section.

38 (2) Biomarker testing must be covered for the purposes of
39 diagnosis, treatment, appropriate management, or ongoing monitoring

1 of an enrollee's disease or condition when the test is supported by
2 medical and scientific evidence including, but not limited to:

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

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

9 (c) Nationally recognized clinical practice guidelines; or

10 (d) Consensus statements.

11 (3) A health plan offered to public employees and their covered
12 dependents shall ensure coverage as required in subsection (2) of
13 this section is provided in a manner that limits disruptions in care
14 including the need for multiple biopsies or biospecimen samples.

15 (4) For the purposes of this section:

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

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

25 (c) "Consensus statements" means statements that are:

26 (i) Developed by an independent, multidisciplinary panel of
27 experts utilizing a transparent methodology and reporting structure
28 and with a conflict of interest policy;

29 (ii) Aimed at specific clinical circumstances; and

30 (iii) Based on the best available evidence for the purpose of
31 optimizing the outcomes of clinical care.

32 (d) "Nationally recognized clinical practice guidelines" means
33 evidence-based clinical practice guidelines that:

34 (i) Are developed by independent organizations or medical
35 professional societies utilizing a transparent methodology and
36 reporting structure and with a conflict of interest policy;

37 (ii) Establish standards of care informed by a systematic review
38 of evidence and an assessment of the benefits and costs of
39 alternative care options; and

40 (iii) Include recommendations intended to optimize patient care.

1 NEW SECTION. **Sec. 3.** A new section is added to chapter 74.09
2 RCW to read as follows:

3 (1) Beginning January 1, 2024, the authority shall provide
4 coverage under this chapter for biomarker testing pursuant to the
5 criteria established under subsection (2) of this section.

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

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

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

16 (c) Nationally recognized clinical practice guidelines; or

17 (d) Consensus statements.

18 (3) The authority shall ensure coverage as required in subsection
19 (2) of this section is provided in a manner that limits disruptions
20 in care including the need for multiple biopsies or biospecimen
21 samples.

22 (4) In administering this program, the authority shall seek any
23 available federal financial participation under the medical
24 assistance program, as codified at Title XIX of the federal social
25 security act, or any other federal funding sources that are now
26 available or may become available.

27 (5) For the purposes of this section:

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

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

37 (c) "Consensus statements" means statements that are:

38 (i) Developed by an independent, multidisciplinary panel of
39 experts utilizing a transparent methodology and reporting structure
40 and with a conflict of interest policy;

- 1 (ii) Aimed at specific clinical circumstances; and
2 (iii) Based on the best available evidence for the purpose of
3 optimizing the outcomes of clinical care.
- 4 (d) "Nationally recognized clinical practice guidelines" means
5 evidence-based clinical practice guidelines that:
- 6 (i) Are developed by independent organizations or medical
7 professional societies utilizing a transparent methodology and
8 reporting structure and with a conflict of interest policy;
- 9 (ii) Establish standards of care informed by a systematic review
10 of evidence and an assessment of the benefits and costs of
11 alternative care options; and
- 12 (iii) Include recommendations intended to optimize patient care.

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