

---

**SUBSTITUTE HOUSE BILL 1450**

---

**State of Washington**

**68th Legislature**

**2023 Regular Session**

**By** House Health Care & Wellness (originally sponsored by Representatives Stonier, Harris, Simmons, Reed, and Macri)

READ FIRST TIME 02/10/23.

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 for stage 1, 2, 3, or 4 cancer and brain cancer pursuant to the  
10 criteria 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 stage 1, 2, 3, or 4 cancer or brain cancer when the  
14 test is supported by medical and scientific evidence including, but  
15 not limited to:

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

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

1 (c) Nationally recognized clinical practice guidelines; or

2 (d) Consensus statements.

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

7 (4) For the purposes of this section:

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

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

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

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

21 (ii) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

35 (1) A health plan offered to public employees and their covered  
36 dependents under this chapter issued or renewed on or after January  
37 1, 2024, shall include coverage for biomarker testing for stage 1, 2,  
38 3, or 4 cancer and brain cancer pursuant to the criteria established  
39 under subsection (2) of this section.

1 (2) Biomarker testing must be covered for the purposes of  
2 diagnosis, treatment, appropriate management, or ongoing monitoring  
3 of an enrollee's stage 1, 2, 3, or 4 cancer or brain cancer when the  
4 test is supported by medical and scientific evidence including, but  
5 not limited to:

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

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

12 (c) Nationally recognized clinical practice guidelines; or

13 (d) Consensus statements.

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

18 (4) For the purposes of this section:

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

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

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

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

32 (ii) Aimed at specific clinical circumstances; and

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

35 (d) "Nationally recognized clinical practice guidelines" means  
36 evidence-based clinical practice guidelines that:

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

1 (ii) Establish standards of care informed by a systematic review  
2 of evidence and an assessment of the benefits and costs of  
3 alternative care options; and

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

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

7 (1) Beginning January 1, 2024, the authority shall provide  
8 coverage under this chapter for biomarker testing for stage 1, 2, 3,  
9 or 4 cancer and brain cancer pursuant to the criteria established  
10 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 stage 1, 2, 3, or 4 cancer or brain cancer when the  
14 test is supported by medical and scientific evidence including, but  
15 not limited to:

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

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

22 (c) Nationally recognized clinical practice guidelines; or

23 (d) Consensus statements.

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

28 (4) In administering this program, the authority shall seek any  
29 available federal financial participation under the medical  
30 assistance program, as codified at Title XIX of the federal social  
31 security act, or any other federal funding sources that are now  
32 available or may become available.

33 (5) For the purposes of this section:

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

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

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

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

9 (ii) Aimed at specific clinical circumstances; and

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

12 (d) "Nationally recognized clinical practice guidelines" means  
13 evidence-based clinical practice guidelines that:

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

17 (ii) Establish standards of care informed by a systematic review  
18 of evidence and an assessment of the benefits and costs of  
19 alternative care options; and

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

--- END ---