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**SECOND SUBSTITUTE HOUSE BILL 1450**

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**State of Washington**

**68th Legislature**

**2024 Regular Session**

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

READ FIRST TIME 01/31/24.

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 2025, 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; or

21 (c) Nationally recognized clinical practice guidelines.

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

4 (4) Biomarker screening tests and biomarker testing that is  
5 investigatory in nature are not required to be covered under this  
6 section.

7 (5) To the extent allowed under this chapter and not prohibited  
8 under this section, health plans may apply prior authorization and  
9 utilization management strategies to biomarker testing.

10 (6) For the purposes of this section:

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

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

20 (c) "Nationally recognized clinical practice guidelines" means  
21 evidence-based clinical practice guidelines that:

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

25 (ii) Establish standards of care informed by a systematic review  
26 of evidence and an assessment of the benefits and costs of  
27 alternative care options; and

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

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

31 (1) A health plan offered to public employees and their covered  
32 dependents under this chapter issued or renewed on or after January  
33 1, 2025, shall include coverage for biomarker testing pursuant to the  
34 criteria established under subsection (2) of this section.

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

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

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

7 (c) Nationally recognized clinical practice guidelines.

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

12 (4) Biomarker screening tests and biomarker testing that is  
13 investigatory in nature are not required to be covered under this  
14 section.

15 (5) To the extent allowed under this chapter and not prohibited  
16 under this section, health plans may apply prior authorization and  
17 utilization management strategies to biomarker testing.

18 (6) 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) "Nationally recognized clinical practice guidelines" means  
29 evidence-based clinical practice guidelines that:

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

33 (ii) Establish standards of care informed by a systematic review  
34 of evidence and an assessment of the benefits and costs of  
35 alternative care options; and

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

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

1 (1) Beginning January 1, 2025, the authority shall provide  
2 coverage under this chapter for biomarker testing pursuant to the  
3 criteria established under subsection (2) of this section.

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

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

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

14 (c) Nationally recognized clinical practice guidelines.

15 (3) The authority shall ensure coverage as required in subsection  
16 (2) of this section is provided in a manner that limits the need for  
17 multiple biopsies or biospecimen samples.

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

23 (5) Biomarker screening tests and biomarker testing that is  
24 investigatory in nature are not required to be covered under this  
25 section.

26 (6) To the extent allowed under this chapter and not prohibited  
27 under this section, health plans may apply prior authorization and  
28 utilization management strategies to biomarker testing.

29 (7) For the purposes of this section:

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

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

39 (c) "Nationally recognized clinical practice guidelines" means  
40 evidence-based clinical practice guidelines that:

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

4 (ii) Establish standards of care informed by a systematic review  
5 of evidence and an assessment of the benefits and costs of  
6 alternative care options; and

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

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