H-2977.2

SECOND SUBSTITUTE HOUSE BILL 1450

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.

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

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

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

(1) For health plans issued or renewed on or after January 1, 2025, a health carrier shall include coverage for biomarker testing pursuant to the criteria established under subsection (2) of this section.

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

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

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

(c) Nationally recognized clinical practice guidelines.

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

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

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

(6) For the purposes of this section:

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

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

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

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

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

(iii) Include recommendations intended to optimize patient care.

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

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

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

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

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

(c) Nationally recognized clinical practice guidelines.

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

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

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

(6) For the purposes of this section:

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

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

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

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

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

(iii) Include recommendations intended to optimize patient care.

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

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

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

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

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

(c) Nationally recognized clinical practice guidelines.

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

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

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

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

(7) For the purposes of this section:

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

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

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

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

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

(iii) Include recommendations intended to optimize patient care.

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