S.154

Introduced by Senators Gulick, Brock, Major and Vyhovsky

Referred to Committee on Finance

Date: May 9, 2025

Subject: Health; health insurance; Medicaid; biomarker testing

Statement of purpose of bill as introduced: This bill proposes to require health insurance and Medicaid coverage for biomarker testing.

An act relating to health insurance coverage for biomarker testing

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 8 V.S.A. § 4088n is added to read:

§ 4088n. COVERAGE FOR BIOMARKER TESTING

(a) As used in this section:

(1) "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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and the statements are based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) "Health insurance plan" means any health insurance policy or health benefit plan offered by a health insurer, as defined in 18 V.S.A. § 9402. The term does not include policies or plans providing coverage for a specified disease or other limited benefit coverage.

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(b) A health insurance plan shall provide coverage for the services of biomarker testing for the purposes of diagnosis, treatment, appropriate management, and ongoing monitoring of a patient's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA);

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

(5) nationally recognized clinical practice guidelines and consensus statements.

(c) The coverage required in subsection (b) of this section shall be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

Sec. 2. 33 V.S.A. § 1901n is added to read:

§ 1901n. MEDICAID COVERAGE FOR BIOMARKER TESTING

(a) As used in this section:

(1) "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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and the statements are based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(b) The Agency of Human Services shall provide Medicaid coverage for the services of biomarker testing for the purposes of diagnosis, treatment, appropriate management, and ongoing monitoring of a patient's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA);

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

(5) nationally recognized clinical practice guidelines and consensus statements.

(c) The Agency of Human Services shall ensure that the Medicaid coverage required in subsection (b) of this section is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

Sec. 3. MEDICAID STATE PLAN AMENDMENT

The Agency of Human Services shall request approval from the Centers for Medicare and Medicaid Services to amend Vermont's Medicaid state plan if

~~necessary to provide coverage for biomarker testing as set forth in Sec. 2 of~~
~~this act.~~

Sec. 4. EFFECTIVE DATES

(a) Sec. 1 (8 V.S.A. § 4088n) shall take effect on January 1, 2026 and shall apply to all health insurance plans issued on and after January 1, 2026 on such date as a health insurer offers, issues, or renews the health insurance plan, but in no event later than January 1, 2027.

(b) Sec. 2 (33 V.S.A. § 1901n) shall take effect on the later of January 1, 2026 or upon approval by the Centers for Medicare and Medicaid Services of the amendment to Vermont's Medicaid state plan as directed in Sec. 3, if an amendment is necessary.

(c) Sec. 3 (Medicaid state plan amendment) and this section shall take effect on passage.

Sec. 1. HEALTH INSURANCE AND MEDICAID COVERAGE FOR BIOMARKER TESTING; DEPARTMENT OF FINANCIAL REGULATION; AGENCY OF HUMAN SERVICES; REPORTS

(a) As used in this section:

(1) "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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests; multiplex panel tests; protein expression analysis; and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and the statements are based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(b) The Department of Financial Regulation and Agency of Human Services shall analyze the costs associated with requiring health insurance coverage and Medicaid coverage, respectively, for biomarker testing for the purposes of diagnosis, treatment, appropriate management, and ongoing monitoring of a patient's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA);

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

(5) nationally recognized clinical practice guidelines and consensus statements.

(c)(1) On or before January 15, 2027, the Department of Financial Regulation shall report to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance on the estimated amount that health insurance premiums would increase if Vermont were to enact legislation requiring health insurance coverage of biomarker testing as set forth in subsection (b) of this section, including the amounts of the State's financial obligations for defrayal of premium increases for qualified health benefit plans pursuant to 45 C.F.R. § 155.170 and for premium increases in the State Employees' Health Benefit Plan.

(2) On or before January 15, 2027, the Agency of Human Services shall report to the House Committee on Health Care and the Senate Committee on Health and Welfare regarding the approvals that would be needed from the Centers for Medicare and Medicaid in order for Vermont Medicaid to cover biomarker testing as set forth in subsection (b) of this section and the costs to the Medicaid program if Vermont were to enact legislation requiring that coverage.

Sec. 2. EFFECTIVE DATE

This act shall take effect on passage.