

1 H.532

2 Introduced by Representative Hango of Berkshire

3 Referred to Committee on

4 Date:

5 Subject: Health; health insurance; biomarker testing

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

8 An act relating to health insurance coverage for biomarker testing

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

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

11 § 4088n. COVERAGE FOR BIOMARKER TESTING

12 (a) As used in this section:

13 (1) “Biomarker” means a characteristic that is objectively measured and
14 evaluated as an indicator of normal biological processes, pathogenic processes,
15 or pharmacologic responses to a specific therapeutic intervention. Biomarkers
16 include gene mutations and protein expression.

17 (2) “Biomarker testing” means the analysis of a patient’s tissue, blood,
18 or other biospecimen for the presence of a biomarker. Biomarker testing
19 includes single-analyte tests, multiplex panel tests, and whole genome
20 sequencing.

1 (3) “Clinical utility” means that a test result provides information that is
2 used in the formulation of a treatment or monitoring strategy that informs a
3 patient’s outcome and impacts one or more clinical decisions. The most
4 appropriate test may include both information that is actionable and some
5 information that cannot be immediately used in the formulation of a clinical
6 decision.

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

13 (5) “Health insurance plan” means any health insurance policy or health
14 benefit plan offered by a health insurer, as defined in 18 V.S.A. § 9402, as well
15 as Medicaid and any other public health care assistance program offered or
16 administered by the State or by any subdivision or instrumentality of the State.
17 The term does not include policies or plans providing coverage for a specified
18 disease or other limited benefit coverage.

19 (6) “Nationally recognized clinical practice guidelines” means evidence-
20 based clinical practice guidelines developed by independent organizations or
21 medical professional societies utilizing a transparent methodology and

1 reporting structure with a conflict of interest policy. Clinical practice
2 guidelines establish standards of care informed by a systematic review of
3 evidence and an assessment of the benefits and costs of alternative care options
4 and include recommendations intended to optimize patient care.

5 (b) A health insurance plan shall provide coverage for the services of
6 biomarker testing for the purposes of diagnosis, treatment, appropriate
7 management, and ongoing monitoring of a patient's disease or condition to
8 guide treatment decisions when the test provides clinical utility, as
9 demonstrated by medical and scientific evidence, including:

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

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

13 (3) warnings and precautions on an FDA-approved drug label;

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

16 determinations; or

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

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

1 Sec. 2. EFFECTIVE DATE

2 This act shall take effect on January 1, 2025 and shall apply to all health
3 insurance plans issued on and after January 1, 2025 on such date as a health
4 insurer offers, issues, or renews the health insurance plan, but in no event later
5 than January 1, 2026.