

**SENATE
STATE OF MINNESOTA
NINETY-SECOND SESSION**

S.F. No. 4610

(SENATE AUTHORS: **UTKE and Draheim**)

DATE
05/22/2022

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OFFICIAL STATUS
Introduction and first reading
Referred to Commerce and Consumer Protection Finance and Policy

1.1 A bill for an act
1.2 relating to insurance; requiring health plans to provide coverage for biomarker
1.3 testing; amending Minnesota Statutes 2020, section 256B.0625, by adding a
1.4 subdivision; proposing coding for new law in Minnesota Statutes, chapter 62Q.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. **62Q.473 BIOMARKER TESTING.**

1.7 Subdivision 1. **Definitions.** (a) For the purposes of this section, the terms defined in this
1.8 subdivision have the meanings given.

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

1.13 (c) "Biomarker testing" means the analysis of an individual's tissue, blood, or other
1.14 biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited
1.15 to single-analyst tests, multiplex panel tests, and whole genome sequencing.

1.16 (d) "Consensus statement" means a statement developed by an independent,
1.17 multidisciplinary panel of experts (1) using a transparent methodology and reporting structure,
1.18 and (2) with a conflict of interest policy. A statement must be applicable to specific clinical
1.19 circumstances and based on the best available evidence.

1.20 (e) "Nationally recognized clinical practice guideline" means an evidence-based clinical
1.21 practice guideline developed by an independent organization or medical professional society
1.22 (1) using a transparent methodology and reporting structure, and (2) with a conflict of

2.1 interest policy. A clinical practice guideline establishes a standard of care informed by a
 2.2 systematic review of evidence and an assessment of the benefits and costs of alternative
 2.3 care options, and includes recommendations to optimize patient care.

2.4 Subd. 2. **Biomarker testing; coverage required.** (a) A health plan company must
 2.5 provide coverage for biomarker testing to diagnose, treat, manage, and monitor illness or
 2.6 disease.

2.7 (b) A health plan company is only required to provide coverage of biomarker testing
 2.8 when the test is supported by medical evidence, including but not limited to:

2.9 (1) nationally recognized clinical practice guidelines;

2.10 (2) consensus statements;

2.11 (3) labeled indications for a United States Food and Drug Administration (FDA)-approved
 2.12 or FDA-cleared test, or indicated tests for an FDA-approved drug; or

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

2.15 (c) Coverage under this section must be provided in a manner that limits disruption of
 2.16 care, including the need for multiple biopsies or biospecimen samples.

2.17 **EFFECTIVE DATE.** This section is effective January 1, 2023, and applies to health
 2.18 plans offered, issued, or renewed on or after that date.

2.19 Sec. 2. Minnesota Statutes 2020, section 256B.0625, is amended by adding a subdivision
 2.20 to read:

2.21 Subd. 68. **Biomarker testing.** Medical assistance covers biomarker testing to diagnose,
 2.22 treat, manage, and monitor illness or disease. Medical assistance coverage must meet the
 2.23 requirements that would otherwise apply to a health plan company under section 62Q.473.

2.24 **EFFECTIVE DATE.** This section is effective January 1, 2023, or upon federal approval,
 2.25 whichever is later.