State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-THIRD SESSION

H. F. No. 1978

02/20/2023 Authored by Reyer, Quam, Hemmingsen-Jaeger, Acomb, Norris and others
The bill was read for the first time and referred to the Committee on Commerce Finance and Policy

A bill for an act

relating to insurance; requiring health plans to provide coverage for biomarker testing; amending Minnesota Statutes 2022, section 256B.0625, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapter 62Q.

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

Section 1. **[62Q.473] BIOMARKER TESTING.**

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

(b) "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 but not limited to known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes, or protein expression.

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

(d) "Clinical utility" means a test provides information that is used to formulate a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include information that is actionable and some information that cannot be immediately used to formulate a clinical decision.

(e) "Consensus statement" means a statement that (1) describes optimal clinical care outcomes, based on the best available evidence, for a specific clinical circumstance; and (2) is developed by an independent, multidisciplinary panel of experts that (i) uses a rigorous and validated development process that includes a transparent methodology and reporting structure, and (ii) strictly adheres to the panel's conflict of interest policy.

(f) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline that (1) establishes a standard of care informed by (i) a systematic review of evidence, and (ii) an assessment of the costs and benefits of alternative care options; and (2) is developed by an independent organization or medical professional society that (i) uses a transparent methodology and reporting structure, and (ii) adheres to a conflict of interest policy. Nationally recognized clinical practice guideline includes recommendations to optimize patient care.

Subd. 2. **Biomarker testing; coverage required.** (a) A health plan company must provide coverage for biomarker testing to diagnose, treat, manage, and monitor illness or disease if the test provides clinical utility. For purposes of this section, a test's clinical utility may be demonstrated by medical and scientific evidence, including but not limited to:

(1) nationally recognized clinical practice guidelines;

(2) consensus statements;

(3) labeled indications for a United States Food and Drug Administration (FDA)-approved or FDA-cleared test, indicated tests for an FDA-approved drug, or adherence to warnings and precautions on FDA-approved drug labels; or

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

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

(c) Nothing in this section prohibits a health plan company from requiring a prior authorization or imposing other utilization controls when approving coverage for biomarker testing for cancer.

EFFECTIVE DATE. This section is effective January 1, 2025, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 2. Minnesota Statutes 2022, section 256B.0625, is amended by adding a subdivision to read:

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

EFFECTIVE DATE. This section is effective January 1, 2025, or upon federal approval, whichever is later.