

616 Fifth Avenue, Suite 106
Belmar, NJ 07719
732-201-4133
CHIEF EXECUTIVE OFFICER: Thomas B. Considine



PRESIDENT: Rep. Deborah Ferguson, AR
VICE PRESIDENT: Rep. Tom Oliverson, TX
TREASURER: Asw. Pamela Hunter, NY
SECRETARY: Sen. Paul Utke, MN

IMMEDIATE PAST PRESIDENTS:
Rep. Matt Lehman, IN
Sen. Travis Holdman, IN

National Council of Insurance Legislators (NCOIL)

Biomarker Testing Insurance Coverage Model Act

**Sponsored by Asw. Pam Hunter (NY) – NCOIL Treasurer*

**Co-sponsored by Sen. Paul Utke (MN) – NCOIL Secretary*

**Adopted by the NCOIL Health Insurance & Long Term Care Issues Committee on July 20, 2023 and the NCOIL Executive Committee on July 22, 2023.*

Table of Contents

Section 1.	Title
Section 2.	Definitions
Section 3.	Health Insurer Requirements
Section 4.	Medicaid Coverage Requirements
Section 5.	Rules
Section 6.	Effective Date

Section 1. Title

This Act shall be known and cited as the “[State] Biomarker Testing Insurance Coverage Act.”

Section 2. Definitions

(a) “Biomarker” means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.

(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 and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(d) “Nationally recognized clinical practice guidelines” as used here are 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 costs of alternative care options and include recommendations intended to optimize patient care.

Section 3. Health Insurer Requirements

(a) Health insurers, nonprofit health service plans, and health maintenance organizations issuing, amending, delivering or renewing a health insurance contract on or after [DATE] shall include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person’s disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

1. labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) of the United States government or indicated tests for an FDA approved drug;
2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
3. Nationally recognized clinical practice guidelines.

(b) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(c) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this Section. Such process shall be made readily accessible on the health insurer’s, nonprofit health service plan’s, or health maintenance organization’s website.

(d) Nothing in this Section shall be construed to require coverage of biomarker testing for screening purposes.

Section 4. Medicaid Coverage Requirements

(a) The State Medical Assistance Program (Medicaid Program) shall cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

1. labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) of the United States government or indicated tests for an FDA approved drug;
2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
3. Nationally recognized clinical practice guidelines.

(b) Risk-bearing entities contracted to the Medicaid Program to deliver services to recipients shall provide biomarker testing at the same scope, duration and frequency as the Medicaid program otherwise provides to enrollees.

(c) The recipient and participating provider shall have access to a clear, readily accessible, and convenient processes to request an exception to a coverage policy of the Medicaid Program or by risk-bearing entities contracted to the Medicaid Program. Such process shall be made readily accessible to all participating providers and enrollees online.

(d) Nothing in this Section shall be construed to require coverage of biomarker testing for screening purposes.

Section 5. Rules

The Commissioner shall adopt rules as necessary to effectuate the provisions of this Act.

Section 6. Effective Date

This Act shall take effect [xxxxx] and shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date.