General Assembly **Substitute Bill No. 6771**

January Session, 2025

* HB06771AGE 030425 *

AN ACT REQUIRING HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective January 1, 2026*) (a) As used in this section:

(1) "Biomarker" means a characteristic, including, but not limited to, a gene mutation or protein expression that can be objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention for a disease or condition.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, including, but not limited to, tests for a single substance, tests for multiple substances, diseases or conditions and whole genome sequencing.

(3) "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. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

(4) "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 that are (A) aimed at specific clinical circumstances, and (B) based on the best available evidence for the purpose of optimizing clinical care outcomes.

(5) "Nationally recognized clinical practice guidelines" means evidence-based guidelines developed by independent organizations or medical professional societies utilizing transparent methodologies and reporting structures and conflict-of-interest policies that (A) establish standards of care informed by a systematic review of evidence and assessments of the benefits and costs of alternative care options, and (B) include recommendations intended to optimize patient care.

(b) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state on or after January 1, 2026, shall provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition, provided such biomarker testing provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to, one or more of the following: (1) Approval or clearance of such test by the federal Food and Drug Administration or recommendations on labels of drugs approved by the federal Food and Drug Administration to conduct such test, (2) national coverage determinations or local coverage determinations for Medicare Administrative Contractors by the Centers for Medicare and Medicaid Services, or (3) nationally recognized clinical practice guidelines and consensus statements. Such policy shall provide such coverage in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(c) Each entity providing such coverage shall establish a clear, readily accessible and convenient process through which an insured or an insured's health care provider may (1) request an exception to a

coverage policy, or (2) dispute an adverse utilization review determination relating to such coverage. Each such entity shall post such process on the Internet web site maintained by such entity.

(d) If prior authorization is required before providing such coverage, each entity providing such coverage or each utilization review entity or other third party acting on behalf of such entity shall approve or deny such prior authorization and notify the insured, the insured's health care provider and any other entity requesting such prior authorization of such approval or denial (1) if the prior authorization is not urgent, as determined by the insured's health care provider, not later than seven days after receiving a prior authorization request, or (2) if the prior authorization is urgent, as determined by the insured's health care provider, not later than seventy-two hours after receiving a prior authorization request.

Sec. 2. (NEW) (*Effective January 1, 2026*) (a) As used in this section:

(1) "Biomarker" means a characteristic, including, but not limited to, a gene mutation or protein expression that can be objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention for a disease or condition.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, including, but not limited to, tests for a single substance, tests for multiple substances, diseases or conditions and whole genome sequencing.

(3) "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. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

(4) "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 that are (A) aimed at specific clinical circumstances, and (B) based on the best available evidence for the purpose of optimizing clinical care outcomes.

(5) "Nationally recognized clinical practice guidelines" means evidence-based guidelines developed by independent organizations or medical professional societies utilizing transparent methodologies and reporting structures and conflict-of-interest policies that (A) establish standards of care informed by a systematic review of evidence and assessments of the benefits and costs of alternative care options, and (B) include recommendations intended to optimize patient care.

(b) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state on or after January 1, 2026, shall provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition, provided such biomarker testing provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to, one or more of the following: (1) Approval or clearance of such test by the federal Food and Drug Administration or recommendations on labels of drugs approved by the federal Food and Drug Administration to conduct such test, (2) national coverage determinations or local coverage determinations for Medicare Administrative Contractors by the Centers for Medicare and Medicaid Services, or (3) nationally recognized clinical practice guidelines and consensus statements. Such policy shall provide such coverage in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(c) Each entity providing such coverage shall establish a clear, readily accessible and convenient process through which an insured or an insured's health care provider may (1) request an exception to a

coverage policy, or (2) dispute an adverse utilization review determination relating to such coverage. Each such entity shall post such process on the Internet web site maintained by such entity.

(d) If prior authorization is required before providing such coverage, each entity providing such coverage or each utilization review entity or other third party acting on behalf of such entity shall approve or deny such prior authorization and notify the insured, the insured's health care provider and any other entity requesting such prior authorization of such approval or denial (1) if the prior authorization is not urgent, as determined by the insured's health care provider, not later than seven days after receiving a prior authorization request, or (2) if the prior authorization is urgent, as determined by the insured's health care provider, not later than seventy-two hours after receiving a prior authorization request.

Sec. 3. (NEW) (*Effective January 1, 2026*) The Insurance Commissioner, in consultation with the Commissioner of Public Health, shall conduct a study regarding the effects of sections 1 and 2 of this act on the insurance industry and on the provision of health care services in the state. Not later than January 1, 2027, and annually thereafter until January 1, 2031, the Insurance Commissioner shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to insurance and real estate and public health regarding the results of such study.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2026*	New section
Sec. 2	*January 1, 2026*	New section
Sec. 3	*January 1, 2026*	New section

AGE *Joint Favorable Subst.*