# House of Representatives

General Assembly

**File No. 107**

*January Session, 2025*

Substitute House Bill No. 6771

*House of Representatives, March 18, 2025*

The Committee on Aging reported through REP. GARIBAY of the 60th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

***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.*

*The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.*

## *OFA Fiscal Note*

### *State Impact:*

| Agency Affected | Fund-Effect | FY 26 $ | FY 27 $ |
|---|---|---|---|
| Insurance Dept. | IF - Cost | None | 65,000 - 80,000 |
| State Comptroller - Fringe Benefits | GF - Potential Cost | Less than 100,000 | Less than 200,000 |
| Resources of the General Fund | GF - Potential Cost | Up to 92,000 | Up to 184,000 |
| Social Services, Dept. | GF - Potential Cost | See Below | See Below |

Note: GF=General Fund; IF=Insurance Fund

### *Municipal Impact:*

| Municipalities | Effect | FY 26 $ | FY 27 $ |
|---|---|---|---|
| Various Municipalities | STATE MANDATE[1] - Potential Cost | See Below | See Below |

### *Explanation*

The bill mandates biomarker coverage, which results in potential costs described below. The bill also requires the Insurance Department to conduct a study on the effects of the coverage mandate, which results in an annual cost of $65,000 to $80,000 in FY 27 through FY 31.

**State Employee Health Plan.** Sections 1 and 2 of the bill result in a

[1] State mandate is defined in Sec. 2-32b(2) of the Connecticut General Statutes, "state mandate" means any state initiated constitutional, statutory or executive action that requires a local government to establish, expand or modify its activities in such a way as to necessitate additional expenditures from local revenues.

potential cost less than $100,000 for the partial year coverage in FY 26 and less than $200,000 annually thereafter to the State Comptroller – Fringe Benefits for the anticipated per member per month increase to the state employee health plan (SEHP) associated with the mandated coverage of biomarker testing. The SEHP currently covers biomarker testing. Premiums for the SEHP are anticipated to increase by $0.10 per member per month, assuming a 5% utilization rate increase.

**Municipalities.** Costs related to the mandated coverage may also be incurred by fully insured municipalities and those participating in the State Partnership Plan (SPP). The mandated coverage of biomarker testing results in a potential cost less than $34,000 for the partial year coverage in FY 26 and less than $69,000 annually thereafter shared proportionately amongst municipalities in the SPP based on enrollment. The SPP currently covers biomarker testing. The potential cost accounts for an increase in utilization, and broader coverage for biomarker tests, which may impact plan premiums.

These estimates neglect any future cost saving offsets, and actual fiscal impacts will be realized in future premiums. Actual costs are dependent on the level of coverage, utilization, and number of those enrolled in each plan. Due to federal law, the coverage requirements will not apply to self-insured municipalities, as they are exempt under Employee Retirement Income Security Act (ERISA).

**Exchange and Covered Connecticut.** Sections 1 and 2 also result in a potential cost to the state of up to $92,000 for the partial year coverage in FY 26 and up to $184,000 annually thereafter to defray additional premium costs for enrollees purchasing health insurance on the state's exchange. This cost is potential as it is incurred to the extent the new coverage requirements for biomarker testing are determined to increase premiums and constitute new state benefit mandates under the federal Affordable Care Act (ACA). Currently, the different plans in the exchange cover biomarker testing. The potential cost accounts for an increase in utilization, and broader coverage for biomarker tests, which may impact plan premiums.

Under the ACA, states are allowed to mandate benefits beyond the federally-defined Essential Health Benefits (EHB) but must pay for that excess coverage. Federal regulations require the state to defray the cost of additional benefits related specific care, treatment or services mandated by state action after December 31, 2011 (except to comply with federal requirements) for all plans sold on the exchange.[2] There are currently 152,042 enrollees in qualified health plans on the exchange, including approximately 42,000 in Covered Connecticut.

To the extent the bill is determined to include a new state benefit mandate that requires defrayal, there would be a cost to the state beginning January 1, 2026.[3] Full year costs would begin in FY 27 and continue annually.

Defrayal costs for Covered Connecticut enrollees would be incurred by the Department of Social Services (DSS), to the extent the bill raises premiums for those enrollees.

Federal regulations allow states to update their EHB benchmark plans, potentially incorporating new benefit mandates without the need for defrayal for plan years beginning on January 1, 2020.[4] If the state integrates biomarker testing into its EHB benchmark and obtains federal approval, these benefits become part of the EHB. As a result, the state would not be required to defray the costs of biomarker testing.

**Study.** Section 3 of the bill requires the Insurance Department to conduct a study regarding the effects of sections 1 and 2 on the insurance industry and the state, beginning in FY 27 and continuing annually for five years. This results in an annual cost of $65,000 to $80,000 associated with hiring a contractor to complete the annual study beginning in FY 27 and ending in FY 31.

[2] 45 CFR 155.170

[3] After determining if the mandate is subject to defrayal, states must reimburse the carriers or the insureds for the excess coverage. The premium costs are to be quantified by each insurer on the exchange and reported to the state.

[4] 45 CFR 156.111

### *The Out Years*

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation, cost of biomarker tests, utilization of biomarker testing, and federal regulations regarding defrayal requirements.

**OLR Bill Analysis**

**sHB 6771**

***AN ACT REQUIRING HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.***

## SUMMARY

This bill requires certain individual and group health insurance policies to cover biomarker testing to diagnose, treat, manage, or monitor an insured's disease or condition, if medical and scientific evidence (e.g., federal Food and Drug Administration approval, Medicare coverage determinations, or nationally recognized clinical guidelines) shows the testing provides clinical utility. The policies must provide coverage in a way that limits any disruptions to the insured's care. The bill also (1) requires health carriers to establish a process for insureds to request an exception to a coverage policy or dispute an adverse utilization review determination (e.g., denial) related to the coverage and (2) sets specific requirements for prior authorization requests.

Under the bill, a "biomarker" is a physical characteristic, including 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. A biomarker test analyzes a patient's tissue, blood, or other biospecimen for a biomarker.

Lastly, the bill requires the insurance commissioner, with the public health commissioner, to study the bill's effects on health care services provided in Connecticut. The insurance commissioner must report the study results to the Insurance and Real Estate and Public Health committees annually beginning by January 1, 2027, until January 1, 2031.

EFFECTIVE DATE: January 1, 2026

## PROCESS FOR POLICY EXCEPTIONS AND COVERAGE APPEALS

The bill requires each health carrier (e.g., insurer or HMO) to establish a clear, readily accessible, and convenient process through which an insured, or his or her health care provider, may request a coverage policy exception or dispute an adverse utilization review determination. Carriers must post these processes on their websites.

## PRIOR AUTHORIZATION REQUESTS

Under the bill, if the health insurance policy requires an insured to receive prior authorization for biomarker testing, the health carrier, associated utilization review entity, or third party acting on the carrier's behalf must approve or deny the prior authorization request within specified deadlines. Specifically, it must notify the insured, his or her health care provider, or any entity requesting the prior authorization of the approval or denial (1) within seven days, if the prior authorization is not urgent, or (2) within 72 hours if it is urgent. Under the bill, the health care provider determines if the authorization is urgent or not.

## BILL APPLICABILITY

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan. Because of the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

## COMMITTEE ACTION

Aging Committee

Joint Favorable Substitute
Yea 13 Nay 0 (03/04/2025)