



General Assembly

***Substitute Bill No. 6771***

*January Session, 2025*



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

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

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

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

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

11      (3) "Clinical utility" means the test result provides information that is  
12      used in the formulation of a treatment or monitoring strategy that  
13      informs a patient's outcome and impacts the clinical decision. The most  
14      appropriate test may include both information that is actionable and  
15      some information that cannot be immediately used in the formulation  
16      of a clinical decision.

17      (4) "Consensus statements" means statements developed by an

18 independent, multidisciplinary panel of experts utilizing a transparent  
19 methodology and reporting structure and with a conflict-of-interest  
20 policy that are (A) aimed at specific clinical circumstances, and (B) based  
21 on the best available evidence for the purpose of optimizing clinical care  
22 outcomes.

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

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

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

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

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

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

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

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

75 (3) "Clinical utility" means the test result provides information that is  
76 used in the formulation of a treatment or monitoring strategy that  
77 informs a patient's outcome and impacts the clinical decision. The most  
78 appropriate test may include both information that is actionable and  
79 some information that cannot be immediately used in the formulation  
80 of a clinical decision.

81 (4) "Consensus statements" means statements developed by an

82 independent, multidisciplinary panel of experts utilizing a transparent  
83 methodology and reporting structure and with a conflict-of-interest  
84 policy that are (A) aimed at specific clinical circumstances, and (B) based  
85 on the best available evidence for the purpose of optimizing clinical care  
86 outcomes.

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

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

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

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

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

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

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

**AGE**      *Joint Favorable Subst.*

**INS**      *Joint Favorable*

