



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*

APP *Joint Favorable*