

House Bill 85 (COMMITTEE SUBSTITUTE)

By: Representatives Cooper of the 45th, Hawkins of the 27th, Lumsden of the 12th, Reese of the 140th, and Frye of the 122nd

A BILL TO BE ENTITLED
AN ACT

1 To amend Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated,
2 relating to general provisions regarding insurance, so as to require health benefit policy
3 coverage for biomarker testing if supported by medical and scientific evidence; to provide
4 for definitions; to provide for requirements; to provide conditions relating to prior
5 authorization; to provide for processes to request exceptions or appeal adverse
6 determinations; to amend Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia
7 Annotated, relating to medical assistance generally, so as to provide for coverage for
8 biomarker testing if supported by medical and scientific evidence; to provide for definitions;
9 to provide for requirements; to provide conditions relating to prior authorization; to provide
10 for processes to request exceptions or appeal adverse determinations; to provide for related
11 matters; to repeal conflicting laws; and for other purposes.

12 **BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:**

13 **SECTION 1.**

14 Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to
15 general provisions regarding insurance, is amended by adding a new Code section to read as
16 follows:

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17 "33-24-59.33.

18 (a) As used in this Code section, the term:

19 (1) 'Biomarker' means a characteristic that is objectively measured and evaluated as an
20 indicator of normal biological processes, pathogenic processes, or pharmacologic
21 responses to a specific therapeutic intervention. Such term includes, but is not limited to,
22 gene mutations, protein expression, known gene-drug interactions for medications, and
23 characteristics of genes.

24 (2) 'Biomarker testing' means the analysis of a patient's tissue, blood, or other
25 biospecimen for the presence of a biomarker. Such term includes, but is not limited to,
26 single-analyte tests, multiplex panel tests, whole genome sequencing, protein expression,
27 whole exome, and whole transcriptome.

28 (3) 'Consensus statements' means statements developed by an independent,
29 multidisciplinary panel of experts utilizing a transparent methodology and reporting
30 structure and with a conflict-of-interest policy. Such statements are aimed at specific
31 clinical circumstances and base the statements on the best available evidence for the
32 purpose of optimizing the outcomes of clinical care.

33 (4) 'Health benefit policy' means any individual or group plan, policy, or contract for
34 healthcare services issued, delivered, issued for delivery, or renewed in this state which
35 provides major medical benefits, including those contracts executed by the State of
36 Georgia on behalf of state employees under Article 1 of Chapter 18 of Title 45, by a
37 health care corporation, health maintenance organization, preferred provider organization,
38 accident and sickness insurer, fraternal benefit society, hospital service corporation,
39 medical service corporation, or other insurer or similar entity.

40 (5) 'Nationally recognized clinical practice guidelines' means evidence based clinical
41 practice guidelines developed by independent organizations or medical professional
42 societies utilizing a transparent methodology and reporting structure and with a
43 conflict-of-interest policy. Such guidelines establish standards of care informed by a

44 systematic review of evidence and an assessment of the benefits and risks of alternative
45 care options and include recommendations intended to optimize patient care.

46 (b) All health benefit policies renewed or issued on or after July 1, 2023, shall include
47 coverage for biomarker testing as provided in this Code section.

48 (c) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate
49 management, or ongoing monitoring of an enrollee's disease or condition when the testing
50 is supported by medical and scientific evidence, including, but not limited to:

51 (1) A labeled indication for a test that has been approved or cleared by the United States
52 Food and Drug Administration (FDA);

53 (2) An indicated test for an FDA approved drug;

54 (3) A national coverage determination made by the federal Centers for Medicare and
55 Medicaid Services or a local coverage determination made by a medicare administrative
56 contractor;

57 (4) Nationally recognized clinical practice guidelines and consensus statements; or

58 (5) Warnings and precautions on FDA approved drugs.

59 (d) Health benefit policies shall ensure biomarker testing coverage is provided in a manner
60 that limits disruptions in care, including the need for multiple biopsies or biospecimen
61 samples.

62 (e) The insurer or similar entity subject to this Code section shall approve or deny a prior
63 authorization request and notify the enrollee and the enrollee's healthcare provider within
64 seven calendar days for nonurgent requests or within 72 hours for urgent requests. If the
65 insurer or similar entity fails to respond in accordance with such time frames, such request
66 shall be deemed approved.

67 (f) Enrollees, healthcare providers, and testing service providers shall have access to a
68 clear, readily accessible, and convenient process to request an exception to a coverage
69 policy or an adverse utilization review determination under a health benefit policy,
70 including, but not limited to, the rights of consumers under Article 2 of Chapter 20A of

71 Title 33, the 'Patient's Right to Independent Review Act.' Such process shall be made
72 readily accessible on the insurer's or similar entity's website."

73 **SECTION 2.**

74 Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to
75 medical assistance generally, is amended by adding a new Code section to read as follows:

76 "49-4-159.2.

77 (a) As used in this Code section, the term:

78 (1) 'Biomarker' means a characteristic that is objectively measured and evaluated as an
79 indicator of normal biological processes, pathogenic processes, or pharmacologic
80 responses to a specific therapeutic intervention. Such term includes, but is not limited to,
81 gene mutations, protein expression, known gene-drug interactions for medications, and
82 characteristics of genes.

83 (2) 'Biomarker testing' means the analysis of a patient's tissue, blood, or other
84 biospecimen for the presence of a biomarker. Such term includes, but is not limited to,
85 single-analyte tests, multiplex panel tests, whole genome sequencing, protein expression,
86 whole exome, and whole transcriptome.

87 (3) 'Consensus statements' means statements developed by an independent,
88 multidisciplinary panel of experts utilizing a transparent methodology and reporting
89 structure and with a conflict-of-interest policy. Such statements are aimed at specific
90 clinical circumstances and base the statements on the best available evidence for the
91 purpose of optimizing the outcomes of clinical care.

92 (4) 'Nationally recognized clinical practice guidelines' means evidence based clinical
93 practice guidelines developed by independent organizations or medical professional
94 societies utilizing a transparent methodology and reporting structure and with a
95 conflict-of-interest policy. Such guidelines establish standards of care informed by a

96 systematic review of evidence and an assessment of the benefits and risks of alternative
97 care options and include recommendations intended to optimize patient care.
98 (b) The department shall provide biomarker testing for Medicaid recipients in accordance
99 with the requirements of this Code section.
100 (c) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate
101 management, or ongoing monitoring of an enrollee's disease or condition when the testing
102 is supported by medical and scientific evidence, including, but not limited to:
103 (1) A labeled indication for a test that has been approved or cleared by the United States
104 Food and Drug Administration (FDA);
105 (2) An indicated test for an FDA approved drug;
106 (3) A national coverage determination made by the federal Centers for Medicare and
107 Medicaid Services or a local coverage determination made by a medicare administrative
108 contractor;
109 (4) Nationally recognized clinical practice guidelines and consensus statements; or
110 (5) Warnings and precautions on FDA approved drugs.
111 (d) Care management organizations shall provide biomarker testing as required by this
112 Code section at the same scope, duration, and frequency as the Medicaid program
113 otherwise provides to recipients of medical assistance.
114 (e) A care management organization or its agent shall approve or deny a prior
115 authorization request and notify the recipient and the provider of medical assistance within
116 seven calendar days for nonurgent requests or within 72 hours for urgent requests. If the
117 care management organization or its agent fails to respond in accordance with such time
118 frames, such request shall be deemed approved.
119 (f) Recipients of medical assistance, providers of medical assistance, and testing service
120 providers shall be afforded the fair hearing rights provided pursuant to Code Section
121 49-4-153 or the state plan provided for in Article 13 of Chapter 5 of Title 49 to request an
122 exception to a coverage policy or an adverse utilization review determination by a care

123 management organization or its agent. Such hearing rights shall be made readily accessible
124 on the department's and care management organization's websites."

125 **SECTION 3.**

126 All laws and parts of laws in conflict with this Act are repealed.