

1 A bill to be entitled
2 An act relating to coverage for biomarker testing;
3 amending s. 110.12303, F.S.; requiring the Department
4 of Management Services to provide coverage of
5 biomarker testing for specified purposes for state
6 employees' state group health insurance plan policies
7 issued on or after a specified date; specifying
8 circumstances under which such coverage may be
9 provided; providing definitions; requiring a clear,
10 convenient, and readily accessible process for
11 authorization requests for biomarker testing;
12 providing construction; amending s. 409.906, F.S.;
13 authorizing the Agency for Health Care Administration
14 to pay for biomarker testing under the Medicaid
15 program for specified purposes, subject to specific
16 appropriations; specifying circumstances under which
17 such payments may be made; providing definitions;
18 requiring a clear, convenient, and readily accessible
19 process for authorization requests for biomarker
20 testing; providing construction; authorizing the
21 agency to seek federal approval for biomarker testing
22 payments; creating s. 409.9745, F.S.; requiring
23 managed care plans under contract with the agency in
24 the Medicaid program to provide coverage for biomarker
25 testing for Medicaid recipients in a certain manner;

26 requiring a clear, convenient, and readily accessible
 27 process for authorization requests for biomarker
 28 testing; providing construction; providing effective
 29 dates.

31 Be It Enacted by the Legislature of the State of Florida:

32
 33 Section 1. Subsection (5) is added to section 110.12303,
 34 Florida Statutes, to read:

35 110.12303 State group insurance program; additional
 36 benefits; price transparency program; reporting.—

37 (5)(a) For state group health insurance plan policies
 38 issued on or after January 1, 2025, the department shall provide
 39 coverage of biomarker testing for the purposes of diagnosis,
 40 treatment, appropriate management, or ongoing monitoring of an
 41 enrollee's disease or condition to guide treatment decisions if
 42 medical and scientific evidence indicates that the biomarker
 43 testing provides clinical utility to the enrollee. Such medical
 44 and scientific evidence includes, but is not limited to:

45 1. A labeled indication for a test approved or cleared by
 46 the United States Food and Drug Administration;

47 2. An indicated test for a drug approved by the United
 48 States Food and Drug Administration;

49 3. A national coverage determination made by the Centers
 50 for Medicare and Medicaid Services or a local coverage

51 determination made by the Medicare Administrative Contractor; or
52 4. A nationally recognized clinical practice guideline. As
53 used in this subparagraph, the term "nationally recognized
54 clinical practice guideline" means an evidence-based clinical
55 practice guideline developed by independent organizations or
56 medical professional societies using a transparent methodology
57 and reporting structure and with a conflict-of-interest policy.
58 Guidelines developed by such organizations or societies
59 establish standards of care informed by a systematic review of
60 evidence and an assessment of the benefits and costs of
61 alternative care options and include recommendations intended to
62 optimize patient care.

63 (b) As used in this subsection, the term:

64 1. "Biomarker" means a defined characteristic that is
65 measured as an indicator of normal biological processes,
66 pathogenic processes, or responses to an exposure or
67 intervention, including therapeutic interventions. The term
68 includes, but is not limited to, molecular, histologic,
69 radiographic, or physiologic characteristics but does not
70 include an assessment of how a patient feels, functions, or
71 survives.

72 2. "Biomarker testing" means an analysis of a patient's
73 tissue, blood, or other biospecimen for the presence of a
74 biomarker. The term includes, but is not limited to, single
75 analyte tests, multiplex panel tests, protein expression, and

76 whole exome, whole genome, and whole transcriptome sequencing
77 performed at a participating in-network laboratory facility that
78 is certified pursuant to the federal Clinical Laboratory
79 Improvement Amendment (CLIA) or that has obtained a CLIA
80 Certificate of Waiver by the United States Food and Drug
81 Administration for the tests.

82 3. "Clinical utility" means the test result provides
83 information that is used in the formulation of a treatment or
84 monitoring strategy that informs a patient's outcome and impacts
85 the clinical decision.

86 (c) Each state group health insurance plan shall provide a
87 clear and convenient process for providers to request
88 authorization for biomarker testing. Such process shall be made
89 readily accessible to all enrollees and participating providers
90 online.

91 (d) This subsection does not require coverage of biomarker
92 testing for screening purposes.

93 Section 2. Effective October 1, 2024, subsection (29) is
94 added to section 409.906, Florida Statutes, to read:

95 409.906 Optional Medicaid services.—Subject to specific
96 appropriations, the agency may make payments for services which
97 are optional to the state under Title XIX of the Social Security
98 Act and are furnished by Medicaid providers to recipients who
99 are determined to be eligible on the dates on which the services
100 were provided. Any optional service that is provided shall be

101 provided only when medically necessary and in accordance with
102 state and federal law. Optional services rendered by providers
103 in mobile units to Medicaid recipients may be restricted or
104 prohibited by the agency. Nothing in this section shall be
105 construed to prevent or limit the agency from adjusting fees,
106 reimbursement rates, lengths of stay, number of visits, or
107 number of services, or making any other adjustments necessary to
108 comply with the availability of moneys and any limitations or
109 directions provided for in the General Appropriations Act or
110 chapter 216. If necessary to safeguard the state's systems of
111 providing services to elderly and disabled persons and subject
112 to the notice and review provisions of s. 216.177, the Governor
113 may direct the Agency for Health Care Administration to amend
114 the Medicaid state plan to delete the optional Medicaid service
115 known as "Intermediate Care Facilities for the Developmentally
116 Disabled." Optional services may include:

117 (29) BIOMARKER TESTING SERVICES.—

118 (a) The agency may pay for biomarker testing for the
119 purposes of diagnosis, treatment, appropriate management, or
120 ongoing monitoring of a recipient's disease or condition to
121 guide treatment decisions if medical and scientific evidence
122 indicates that the biomarker testing provides clinical utility
123 to the recipient. Such medical and scientific evidence includes,
124 but is not limited to:

125 1. A labeled indication for a test approved or cleared by

126 | the Unites States Food and Drug Administration;
 127 | 2. An indicated test for a drug approved by the United
 128 | States Food and Drug Administration;
 129 | 3. A national coverage determination made by the Centers
 130 | for Medicare and Medicaid Services or a local coverage
 131 | determination made by the Medicare Administrative Contractor; or
 132 | 4. A nationally recognized clinical practice guideline. As
 133 | used in this subparagraph, the term "nationally recognized
 134 | clinical practice guideline" means an evidence-based clinical
 135 | practice guideline developed by independent organizations or
 136 | medical professional societies using a transparent methodology
 137 | and reporting structure and with a conflict-of-interest policy.
 138 | Guidelines developed by such organizations or societies
 139 | establish standards of care informed by a systematic review of
 140 | evidence and an assessment of the benefits and costs of
 141 | alternative care options and include recommendations intended to
 142 | optimize patient care.
 143 | (b) As used in this subsection, the term:
 144 | 1. "Biomarker" means a defined characteristic that is
 145 | measured as an indicator of normal biological processes,
 146 | pathogenic processes, or responses to an exposure or
 147 | intervention, including therapeutic interventions. The term
 148 | includes, but is not limited to, molecular, histologic,
 149 | radiographic, or physiologic characteristics but does not
 150 | include an assessment of how a patient feels, functions, or

151 survives.

152 2. "Biomarker testing" means an analysis of a patient's
153 tissue, blood, or other biospecimen for the presence of a
154 biomarker. The term includes, but is not limited to, single
155 analyte tests, multiplex panel tests, protein expression, and
156 whole exome, whole genome, and whole transcriptome sequencing
157 performed at a participating in-network laboratory facility that
158 is certified pursuant to the federal Clinical Laboratory
159 Improvement Amendment (CLIA) or that has obtained a CLIA
160 Certificate of Waiver by the United States Food and Drug
161 Administration for the tests.

162 3. "Clinical utility" means the test result provides
163 information that is used in the formulation of a treatment or
164 monitoring strategy that informs a patient's outcome and impacts
165 the clinical decision.

166 (c) A recipient and participating provider shall have
167 access to a clear and convenient process to request
168 authorization for biomarker testing as provided under this
169 subsection. Such process shall be made readily accessible to all
170 recipients and participating providers online.

171 (d) This subsection does not require coverage of biomarker
172 testing for screening purposes.

173 (e) The agency may seek federal approval necessary to
174 implement this subsection.

175 Section 3. Effective October 1, 2024, section 409.9745,

176 Florida Statutes, is created to read:

177 409.9745 Managed care plan biomarker testing.-

178 (1) A managed care plan must provide coverage for
179 biomarker testing for recipients, as authorized under s.
180 409.906, at the same scope, duration, and frequency as the
181 Medicaid program provides for other medically necessary
182 treatments.

183 (2) A recipient and health care provider shall have access
184 to a clear and convenient process to request authorization for
185 biomarker testing as provided under this section. Such process
186 shall be made readily accessible on the website of the managed
187 care plan.

188 (3) This section does not require coverage of biomarker
189 testing for screening purposes.

190 Section 4. Except as otherwise expressly provided in this
191 act, this act shall take effect July 1, 2024.