

1                                   A bill to be entitled  
2           An act relating to coverage for biomarker testing;  
3           amending s. 409.906, F.S.; authorizing the Agency for  
4           Health Care Administration to pay for biomarker  
5           testing under the Medicaid program for specified  
6           purposes, subject to specific appropriations;  
7           specifying circumstances under which such payments may  
8           be made; providing definitions; requiring a clear,  
9           readily accessible, and convenient process for  
10          authorization requests for biomarker testing;  
11          providing construction; authorizing the agency to seek  
12          federal approval for biomarker testing payments;  
13          creating s. 409.9745, F.S.; requiring managed care  
14          plans under contract with the agency to provide  
15          services in the Medicaid program to provide coverage  
16          for biomarker testing for Medicaid recipients in a  
17          certain manner; requiring a clear, readily accessible,  
18          and convenient process for authorization requests for  
19          biomarker testing; providing construction; creating  
20          ss. 627.64183, 627.66133, and 641.31093, F.S.;  
21          providing definitions; requiring certain individual  
22          health insurance policies; group, blanket, and  
23          franchise health insurance policies; and health  
24          maintenance contracts, respectively, to provide  
25          coverage for biomarker testing for certain purposes;

26 specifying circumstances under which such coverage may  
 27 be provided; requiring a clear, readily accessible,  
 28 and convenient process for authorization requests for  
 29 biomarker testing; providing construction; providing  
 30 an effective date.

31

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

33

34 Section 1. Subsection (29) is added to section 409.906,  
 35 Florida Statutes, to read:

36 409.906 Optional Medicaid services.—Subject to specific  
 37 appropriations, the agency may make payments for services which  
 38 are optional to the state under Title XIX of the Social Security  
 39 Act and are furnished by Medicaid providers to recipients who  
 40 are determined to be eligible on the dates on which the services  
 41 were provided. Any optional service that is provided shall be  
 42 provided only when medically necessary and in accordance with  
 43 state and federal law. Optional services rendered by providers  
 44 in mobile units to Medicaid recipients may be restricted or  
 45 prohibited by the agency. Nothing in this section shall be  
 46 construed to prevent or limit the agency from adjusting fees,  
 47 reimbursement rates, lengths of stay, number of visits, or  
 48 number of services, or making any other adjustments necessary to  
 49 comply with the availability of moneys and any limitations or  
 50 directions provided for in the General Appropriations Act or

51 chapter 216. If necessary to safeguard the state's systems of  
52 providing services to elderly and disabled persons and subject  
53 to the notice and review provisions of s. 216.177, the Governor  
54 may direct the Agency for Health Care Administration to amend  
55 the Medicaid state plan to delete the optional Medicaid service  
56 known as "Intermediate Care Facilities for the Developmentally  
57 Disabled." Optional services may include:

58 (29) BIOMARKER TESTING SERVICES.—

59 (a) The agency may pay for biomarker testing for the  
60 purposes of diagnosis, treatment, appropriate management, or  
61 ongoing monitoring of a recipient's disease or condition to  
62 guide treatment decisions if medical and scientific evidence  
63 indicates that the biomarker testing provides clinical utility  
64 to the recipient. Such medical and scientific evidence includes,  
65 but is not limited to:

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

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

70 3. A national coverage determination made by the Centers  
71 for Medicare and Medicaid Services or a local coverage  
72 determination made by the Medicare Administrative Contractor; or

73 4. A nationally recognized clinical practice guideline. As  
74 used in this subparagraph, the term "nationally recognized  
75 clinical practice guideline" means an evidence-based clinical

76 practice guideline developed by independent organizations or  
77 medical professional societies using a transparent methodology  
78 and reporting structure and with a conflict-of-interest policy.  
79 Guidelines developed by such organizations or societies  
80 establish standards of care informed by a systematic review of  
81 evidence and an assessment of the benefits and costs of  
82 alternative care options and include recommendations intended to  
83 optimize patient care.

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

85 1. "Biomarker" means a defined characteristic that is  
86 measured as an indicator of normal biological processes,  
87 pathogenic processes, or responses to an exposure or  
88 intervention, including therapeutic interventions. The term  
89 includes, but is not limited to, molecular, histologic,  
90 radiographic, or physiologic characteristics but does not  
91 include an assessment of how a patient feels, functions, or  
92 survives.

93 2. "Biomarker testing" means an analysis of a patient's  
94 tissue, blood, or other biospecimen for the presence of a  
95 biomarker. The term includes, but is not limited to, single  
96 analyte tests, multiplex panel tests, protein expression, and  
97 whole exome, whole genome, and whole transcriptome sequencing  
98 performed at a participating in-network laboratory facility that  
99 is certified pursuant to the federal Clinical Laboratory  
100 Improvement Amendment (CLIA) or that has obtained a CLIA

101 Certificate of Waiver by the United States Food and Drug  
102 Administration for the tests.

103 3. "Clinical utility" means the test result provides  
104 information that is used in the formulation of a treatment or  
105 monitoring strategy that informs a patient's outcome and impacts  
106 the clinical decision.

107 (c) A recipient and participating provider shall have  
108 access to a clear and convenient process to request  
109 authorization for biomarker testing as provided under this  
110 subsection. Such process shall be made readily accessible to all  
111 recipients and participating providers online.

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

114 (e) The agency may seek federal approval necessary to  
115 implement this subsection.

116 Section 2. Section 409.9745, Florida Statutes, is created  
117 to read:

118 409.9745 Managed care plan biomarker testing.-

119 (1) A managed care plan must provide coverage for  
120 biomarker testing for recipients, as authorized under s.  
121 409.906, at the same scope, duration, and frequency as the  
122 Medicaid program provides for other medically necessary  
123 treatments.

124 (2) A recipient and health care provider shall have access  
125 to a clear and convenient process to request authorization for

126 biomarker testing as provided under this section. Such process  
127 shall be made readily accessible on the website of the managed  
128 care plan.

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

131 Section 3. Section 627.64183, Florida Statutes, is created  
132 to read:

133 627.64183 Coverage for biomarker testing.-

134 (1) As used in this section, the term:

135 (a) "Biomarker" means a defined characteristic that is  
136 measured as an indicator of normal biological processes,  
137 pathogenic processes, or responses to an exposure or  
138 intervention, including therapeutic interventions. The term  
139 includes, but is not limited to, molecular, histologic,  
140 radiographic, or physiologic characteristics but does not  
141 include an assessment of how a patient feels, functions, or  
142 survives.

143 (b) "Biomarker testing" means an analysis of a patient's  
144 tissue, blood, or other biospecimen for the presence of a  
145 biomarker. The term includes, but is not limited to, single  
146 analyte tests, multiplex panel tests, protein expression, and  
147 whole exome, whole genome, and whole transcriptome sequencing  
148 performed at a participating in-network laboratory facility that  
149 is certified pursuant to the federal Clinical Laboratory  
150 Improvement Amendment (CLIA) or that has obtained a CLIA

151 Certificate of Waiver by the United States Food and Drug  
152 Administration for the tests.

153 (c) "Clinical utility" means the test result provides  
154 information that is used in the formulation of a treatment or  
155 monitoring strategy that informs a patient's outcome and impacts  
156 the clinical decision.

157 (2) A health insurance policy or a nonprofit health  
158 service plan that covers a resident of this state and that is  
159 issued, amended, delivered, or renewed in this state on or after  
160 January 1, 2025, must provide coverage for biomarker testing for  
161 the purposes of diagnosis, treatment, appropriate management, or  
162 ongoing monitoring of an insured's disease or condition to guide  
163 treatment decisions if medical and scientific evidence indicates  
164 that the biomarker testing provides clinical utility to the  
165 insured. Such medical and scientific evidence includes, but is  
166 not limited to:

167 (a) A labeled indication for a test approved or cleared by  
168 the United States Food and Drug Administration;

169 (b) An indicated test for a drug approved by the United  
170 States Food and Drug Administration;

171 (c) A national coverage determination made by the Centers  
172 for Medicare and Medicaid Services or a local coverage  
173 determination made by the Medicare Administrative Contractor; or

174 (d) A nationally recognized clinical practice guideline.  
175 As used in this paragraph, the term "nationally recognized

176 clinical practice guideline" means an evidence-based clinical  
177 practice guideline developed by independent organizations or  
178 medical professional societies using a transparent methodology  
179 and reporting structure and with a conflict-of-interest policy.  
180 Guidelines developed by such organizations or societies  
181 establish standards of care informed by a systematic review of  
182 evidence and an assessment of the benefits and costs of  
183 alternative care options and include recommendations intended to  
184 optimize patient care.

185 (3) The coverage under subsection (2) shall be provided in  
186 a manner that limits disruptions in care, including, but not  
187 limited to, the need for multiple biopsies or biospecimen  
188 samples.

189 (4) The insured and the insured's ordering or prescribing  
190 health care provider shall have access to a clear and convenient  
191 process to request authorization for biomarker testing as  
192 provided under this section. Such process shall be made readily  
193 accessible on the website of the health insurer and nonprofit  
194 health service plan.

195 (5) This section does not require coverage of biomarker  
196 testing for screening purposes.

197 Section 4. Section 627.66133, Florida Statutes, is created  
198 to read:

199 627.66133 Coverage for biomarker testing.—

200 (1) As used in this section, the term:



201        (a) "Biomarker" means a defined characteristic that is  
202 measured as an indicator of normal biological processes,  
203 pathogenic processes, or responses to an exposure or  
204 intervention, including therapeutic interventions. The term  
205 includes, but is not limited to, molecular, histologic,  
206 radiographic, or physiologic characteristics but does not  
207 include an assessment of how a patient feels, functions, or  
208 survives.

209        (b) "Biomarker testing" means an analysis of a patient's  
210 tissue, blood, or other biospecimen for the presence of a  
211 biomarker. The term includes, but is not limited to, single  
212 analyte tests, multiplex panel tests, protein expression, and  
213 whole exome, whole genome, and whole transcriptome sequencing  
214 performed at a participating in-network laboratory facility that  
215 is certified pursuant to the federal Clinical Laboratory  
216 Improvement Amendment (CLIA) or that has obtained a CLIA  
217 Certificate of Waiver by the United States Food and Drug  
218 Administration for the tests.

219        (c) "Clinical utility" means the test result provides  
220 information that is used in the formulation of a treatment or  
221 monitoring strategy that informs a patient's outcome and impacts  
222 the clinical decision.

223        (2) A group, blanket, or franchise health insurance policy  
224 or a nonprofit health service plan that covers a resident of  
225 this state and that is issued, amended, delivered, or renewed in

226 this state on or after January 1, 2025, must provide coverage  
227 for biomarker testing for the purposes of diagnosis, treatment,  
228 appropriate management, or ongoing monitoring of an insured's  
229 disease or condition to guide treatment decisions if medical and  
230 scientific evidence indicates that the biomarker testing  
231 provides clinical utility to the insured. Such medical and  
232 scientific evidence includes, but is not limited to:

233 (a) A labeled indication for a test approved or cleared by  
234 the United States Food and Drug Administration;

235 (b) An indicated test for a drug approved by the United  
236 States Food and Drug Administration;

237 (c) A national coverage determination made by the Centers  
238 for Medicare and Medicaid Services or a local coverage  
239 determination made by the Medicare Administrative Contractor; or

240 (d) A nationally recognized clinical practice guideline.

241 As used in this paragraph, the term "nationally recognized  
242 clinical practice guideline" means an evidence-based clinical  
243 practice guideline developed by independent organizations or  
244 medical professional societies using a transparent methodology  
245 and reporting structure and with a conflict-of-interest policy.  
246 Guidelines developed by such organizations or societies  
247 establish standards of care informed by a systematic review of  
248 evidence and an assessment of the benefits and costs of  
249 alternative care options and include recommendations intended to  
250 optimize patient care.

251 (3) The coverage under subsection (2) shall be provided in  
252 a manner that limits disruptions in care, including, but not  
253 limited to, the need for multiple biopsies or biospecimen  
254 samples.

255 (4) The insured and the insured's ordering or prescribing  
256 health care provider shall have access to a clear and convenient  
257 process to request authorization for biomarker testing as  
258 provided under this section. Such process shall be made readily  
259 accessible on the website of the health insurer and nonprofit  
260 health service plan.

261 (5) This section does not require coverage of biomarker  
262 testing for screening purposes.

263 Section 5. Section 641.31093, Florida Statutes, is created  
264 to read:

265 641.31093 Coverage for biomarker testing.-

266 (1) As used in this section, the term:

267 (a) "Biomarker" means a defined characteristic that is  
268 measured as an indicator of normal biological processes,  
269 pathogenic processes, or responses to an exposure or  
270 intervention, including therapeutic interventions. The term  
271 includes, but is not limited to, molecular, histologic,  
272 radiographic, or physiologic characteristics but does not  
273 include an assessment of how a patient feels, functions, or  
274 survives.

275 (b) "Biomarker testing" means an analysis of a patient's

276 tissue, blood, or other biospecimen for the presence of a  
277 biomarker. The term includes, but is not limited to, single  
278 analyte tests, multiplex panel tests, protein expression, and  
279 whole exome, whole genome, and whole transcriptome sequencing  
280 performed at a participating in-network laboratory facility that  
281 is certified pursuant to the federal Clinical Laboratory  
282 Improvement Amendment (CLIA) or that has obtained a CLIA  
283 Certificate of Waiver by the United States Food and Drug  
284 Administration for the tests.

285 (c) "Clinical utility" means the test result provides  
286 information that is used in the formulation of a treatment or  
287 monitoring strategy that informs a patient's outcome and impacts  
288 the clinical decision.

289 (2) A health maintenance contract or a nonprofit health  
290 service plan that covers a resident of this state and that is  
291 issued, amended, delivered, or renewed in this state on or after  
292 January 1, 2025, must provide coverage for biomarker testing for  
293 the purposes of diagnosis, treatment, appropriate management, or  
294 ongoing monitoring of a subscriber's disease or condition to  
295 guide treatment decisions if medical and scientific evidence  
296 indicates that the biomarker testing provides clinical utility  
297 to the subscriber. Such medical and scientific evidence  
298 includes, but is not limited to:

299 (a) A labeled indication for a test approved or cleared by  
300 the United States Food and Drug Administration;

301 (b) An indicated test for a drug approved by the United  
 302 States Food and Drug Administration;

303 (c) A national coverage determination made by the Centers  
 304 for Medicare and Medicaid Services or a local coverage  
 305 determination made by the Medicare Administrative Contractor; or

306 (d) A nationally recognized clinical practice guideline.

307 As used in this paragraph, the term "nationally recognized  
 308 clinical practice guideline" means an evidence-based clinical  
 309 practice guideline developed by independent organizations or  
 310 medical professional societies using a transparent methodology  
 311 and reporting structure and with a conflict-of-interest policy.  
 312 Guidelines developed by such organizations or societies  
 313 establish standards of care informed by a systematic review of  
 314 evidence and an assessment of the benefits and costs of  
 315 alternative care options and include recommendations intended to  
 316 optimize patient care.

317 (3) The coverage under subsection (2) shall be provided in  
 318 a manner that limits disruptions in care, including, but not  
 319 limited to, the need for multiple biopsies or biospecimen  
 320 samples.

321 (4) The subscriber and the subscriber's ordering or  
 322 prescribing health care provider shall have access to a clear  
 323 and convenient process to request authorization for biomarker  
 324 testing as provided under this section. Such process shall be  
 325 made readily accessible on the website of the health maintenance

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326 | organization and nonprofit health service plan.

327 | (5) This section does not require coverage of biomarker  
328 | testing for screening purposes.

329 | Section 6. This act shall take effect July 1, 2024.