

By Senator Wright

8-01279-23

20231218__

1 A bill to be entitled
2 An act relating to biomarker testing; amending s.
3 409.905, F.S.; requiring the Agency for Health Care
4 Administration to pay for biomarker testing under the
5 state Medicaid program for specified purposes;
6 defining terms; specifying tests and circumstances for
7 testing which are deemed covered; requiring certain
8 entities contracted with the program to provide
9 coverage of biomarker testing in the same manner as
10 the program provides to its recipients; requiring the
11 agency to act on a prior authorization request for
12 biomarker testing and notify specified parties within
13 specified timeframes, if the program requires such
14 utilization review procedures; requiring the agency to
15 provide a clear, readily accessible, and convenient
16 process on its website for requesting an exception to
17 the terms of coverage or to appeal certain adverse
18 utilization review determinations; creating ss.
19 627.64055, 627.6614, and 641.31078, F.S.; defining
20 terms; beginning on a specified date, requiring
21 individual health insurance policies; group, blanket,
22 and franchise health insurance policies; and health
23 maintenance contracts, respectively, to provide
24 coverage for biomarker testing under certain
25 circumstances; specifying tests and circumstances for
26 testing which are deemed covered; requiring coverage
27 to be provided in a manner that limits disruption in
28 care; requiring insurers and health maintenance
29 organizations, as applicable, to act on a prior

8-01279-23

20231218__

30 authorization request and notify specified parties
31 within specified timeframes if they require such
32 utilization review procedures; requiring insurers and
33 health maintenance organizations, as applicable, to
34 provide a clear, readily accessible, and convenient
35 process on their websites for requesting exceptions to
36 policy or contract terms, as applicable, and for
37 appealing certain adverse utilization review
38 determinations; providing an effective date.
39

40 Be It Enacted by the Legislature of the State of Florida:
41

42 Section 1. Subsection (13) is added to section 409.905,
43 Florida Statutes, to read:

44 409.905 Mandatory Medicaid services.—The agency may make
45 payments for the following services, which are required of the
46 state by Title XIX of the Social Security Act, furnished by
47 Medicaid providers to recipients who are determined to be
48 eligible on the dates on which the services were provided. Any
49 service under this section shall be provided only when medically
50 necessary and in accordance with state and federal law.
51 Mandatory services rendered by providers in mobile units to
52 Medicaid recipients may be restricted by the agency. Nothing in
53 this section shall be construed to prevent or limit the agency
54 from adjusting fees, reimbursement rates, lengths of stay,
55 number of visits, number of services, or any other adjustments
56 necessary to comply with the availability of moneys and any
57 limitations or directions provided for in the General
58 Appropriations Act or chapter 216.

8-01279-23

20231218__

59 (13) BIOMARKER TESTING SERVICES.—The agency shall pay for
60 biomarker testing for diagnosis, treatment, management, and
61 ongoing monitoring of an insured’s disease or condition if use
62 of the test is supported by medical and scientific evidence.

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

64 1. “Biomarker” means a characteristic that is objectively
65 measured and evaluated as an indicator of normal biological
66 processes, pathogenic processes, or pharmacologic responses to a
67 specific therapeutic intervention, including known gene-drug
68 interactions for medications being considered for use or already
69 being administered. The term includes, but is not limited to,
70 gene mutations, characteristics of genes, and protein
71 expression.

72 2. “Biomarker testing” means the analysis of a patient’s
73 tissue, blood, or other biological specimen for the presence of
74 a biomarker. The term includes, but is not limited to, single-
75 analyte tests, multiplex panel tests, protein expression
76 analysis, and whole exome, whole genome, and whole transcriptome
77 sequencing.

78 3. “Consensus statements” means statements developed by an
79 independent, multidisciplinary panel of experts using a
80 transparent methodology and reporting structure and with a
81 conflict of interest policy. These statements address specific
82 clinical circumstances, and the experts base these statements on
83 the best available evidence to optimize the outcomes of clinical
84 care.

85 4. “Nationally recognized clinical practice guidelines”
86 means evidence-based clinical practice guidelines developed by
87 independent organizations or medical professional societies

8-01279-23

20231218__

88 using a transparent methodology and reporting structure and with
89 a conflict of interest policy. These guidelines establish
90 standards of care informed by a systematic review of evidence
91 and an assessment of the benefits and risks of alternative care
92 options and include recommendations intended to optimize patient
93 care.

94 (b) For purposes of coverage of biomarker testing, all of
95 the following tests and circumstances for testing are deemed to
96 be supported by medical and scientific evidence:

97 1. A test approved or cleared by the United States Food and
98 Drug Administration.

99 2. Indicated tests for a drug approved by the United States
100 Food and Drug Administration.

101 3. Warnings and precautions on the label for a drug
102 approved by the United States Food and Drug Administration.

103 4. Tests approved under the Centers for Medicare and
104 Medicaid Services national coverage determination process or the
105 local coverage determination process of a Medicare
106 Administrative Contractor.

107 5. Nationally recognized clinical practice guidelines and
108 consensus statements.

109 (c) Risk-bearing entities contracted with the program to
110 deliver services to recipients must provide coverage of
111 biomarker testing in the same manner as the program otherwise
112 provides to recipients.

113 (d) If utilization review for biomarker testing is
114 required, the program, utilization review entity, or third party
115 acting on behalf of the program must approve or deny a prior
116 authorization request and notify the enrollee, the enrollee's

8-01279-23

20231218__

117 health care provider, and any entity requesting authorization of
118 the service within 72 hours after a nonurgent request and within
119 24 hours after an urgent request.

120 (e) The agency must provide a clear, readily accessible,
121 and convenient process on its website for an enrollee or a
122 provider to request an exception to the terms of coverage or to
123 appeal an adverse utilization review determination relating to
124 biomarker testing services.

125 Section 2. Section 627.64055, Florida Statutes, is created
126 to read:

127 627.64055 Coverage of biomarker testing.-

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

129 (a) "Biomarker" means a characteristic that is objectively
130 measured and evaluated as an indicator of normal biological
131 processes, pathogenic processes, or pharmacologic responses to a
132 specific therapeutic intervention, including known gene-drug
133 interactions for medications being considered for use or already
134 being administered. The term includes, but is not limited to,
135 gene mutations, characteristics of genes, and protein
136 expression.

137 (b) "Biomarker testing" means the analysis of a patient's
138 tissue, blood, or other biological specimen for the presence of
139 a biomarker. The term includes, but is not limited to, single-
140 analyte tests, multiplex panel tests, protein expression
141 analysis, and whole exome, whole genome, and whole transcriptome
142 sequencing.

143 (c) "Consensus statements" means statements developed by an
144 independent, multidisciplinary panel of experts using a
145 transparent methodology and reporting structure and with a

8-01279-23

20231218__

146 conflict of interest policy. These statements address specific
147 clinical circumstances, and the experts base these statements on
148 the best available evidence to optimize the outcomes of clinical
149 care.

150 (d) "Nationally recognized clinical practice guidelines"
151 means evidence-based clinical practice guidelines developed by
152 independent organizations or medical professional societies
153 using a transparent methodology and reporting structure and with
154 a conflict of interest policy. These guidelines establish
155 standards of care informed by a systematic review of evidence
156 and an assessment of the benefits and risks of alternative care
157 options and include recommendations intended to optimize patient
158 care.

159 (2) A health insurance policy issued, delivered, or renewed
160 in this state on or after July 1, 2023, must provide coverage
161 for biomarker testing for diagnosis, treatment, management, or
162 ongoing monitoring of an insured's disease or condition if use
163 of the test is supported by medical and scientific evidence. For
164 purposes of coverage, all of the following tests and
165 circumstances for testing are deemed to be supported by medical
166 and scientific evidence:

167 (a) A test approved or cleared by the United States Food
168 and Drug Administration.

169 (b) Indicated tests for a drug approved by the United
170 States Food and Drug Administration.

171 (c) Warnings and precautions on the label for a drug
172 approved by the United States Food and Drug Administration.

173 (d) Tests approved under the Centers for Medicare and
174 Medicaid Services national coverage determination process or the

8-01279-23

20231218__

175 local coverage determination process of a Medicare
176 Administrative Contractor.

177 (e) Nationally recognized clinical practice guidelines and
178 consensus statements.

179 (3) Insurers must ensure that coverage of biomarker testing
180 is provided in a manner that limits disruptions in care,
181 including, but not limited to, coverage of biomarker testing for
182 multiple biopsies or biological specimen samples if needed.

183 (4) If utilization review for biomarker testing is
184 required, the insurer, utilization review entity, or third party
185 acting on behalf of the insurer must approve or deny a prior
186 authorization request and notify the insured, the insured's
187 health care provider, and any entity requesting authorization of
188 the service within 72 hours after a nonurgent request and within
189 24 hours after an urgent request.

190 (5) Insurers must provide a clear, readily accessible, and
191 convenient process on their websites for requesting an exception
192 to the terms of a policy or for appealing an adverse utilization
193 review determination relating to biomarker testing services.

194 Section 3. Section 627.6614, Florida Statutes, is created
195 to read:

196 627.6614 Coverage of biomarker testing.—

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

198 (a) "Biomarker" means a characteristic that is objectively
199 measured and evaluated as an indicator of normal biological
200 processes, pathogenic processes, or pharmacologic responses to a
201 specific therapeutic intervention, including known gene-drug
202 interactions for medications being considered for use or already
203 being administered. The term includes, but is not limited to,

8-01279-23

20231218__

204 gene mutations, characteristics of genes, and protein
205 expression.

206 (b) "Biomarker testing" means the analysis of a patient's
207 tissue, blood, or other biological specimen for the presence of
208 a biomarker. The term includes, but is not limited to, single-
209 analyte tests, multiplex panel tests, protein expression
210 analysis, and whole exome, whole genome, and whole transcriptome
211 sequencing.

212 (c) "Consensus statements" means statements developed by an
213 independent, multidisciplinary panel of experts using a
214 transparent methodology and reporting structure and with a
215 conflict of interest policy. These statements address specific
216 clinical circumstances, and the experts base these statements on
217 the best available evidence to optimize the outcomes of clinical
218 care.

219 (d) "Nationally recognized clinical practice guidelines"
220 means evidence-based clinical practice guidelines developed by
221 independent organizations or medical professional societies
222 using a transparent methodology and reporting structure and with
223 a conflict of interest policy. These guidelines establish
224 standards of care informed by a systematic review of evidence
225 and an assessment of the benefits and risks of alternative care
226 options and include recommendations intended to optimize patient
227 care.

228 (2) A group, blanket, or franchise health insurance policy
229 issued, delivered, or renewed in this state on or after July 1,
230 2023, must provide coverage for biomarker testing for diagnosis,
231 treatment, management, or ongoing monitoring of an insured's
232 disease or condition if use of the test is supported by medical

8-01279-23

20231218__

233 and scientific evidence. For purposes of coverage, all of the
234 following tests and circumstances for testing are deemed to be
235 supported by medical and scientific evidence:

236 (a) A test approved or cleared by the United States Food
237 and Drug Administration.

238 (b) Indicated tests for a drug approved by the United
239 States Food and Drug Administration.

240 (c) Warnings and precautions on the label for a drug
241 approved by the United States Food and Drug Administration.

242 (d) Tests approved under the Centers for Medicare and
243 Medicaid Services' national coverage determination process or
244 the local coverage determination process of a Medicare
245 Administrative Contractor.

246 (e) Nationally recognized clinical practice guidelines and
247 consensus statements.

248 (3) Insurers must ensure that coverage of biomarker testing
249 is provided in a manner that limits disruptions in care,
250 including, but not limited to, coverage of biomarker testing for
251 multiple biopsies or biological specimen samples if needed.

252 (4) If utilization review for biomarker testing is
253 required, the insurer, utilization review entity, or third party
254 acting on behalf of the insurer must approve or deny a prior
255 authorization request and notify the insured, the insured's
256 health care provider, and any entity requesting authorization of
257 the service within 72 hours after a nonurgent request and within
258 24 hours after an urgent request.

259 (5) Insurers must provide a clear, readily accessible, and
260 convenient process on their websites for requesting an exception
261 to the terms of a policy or for appealing an adverse utilization

8-01279-23

20231218__

262 review determination relating to biomarker testing services.

263 Section 4. Section 641.31078, Florida Statutes, is created
264 to read:

265 641.31078 Coverage of biomarker testing.-

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

267 (a) "Biomarker" means a characteristic that is objectively
268 measured and evaluated as an indicator of normal biological
269 processes, pathogenic processes, or pharmacologic responses to a
270 specific therapeutic intervention, including known gene-drug
271 interactions for medications being considered for use or already
272 being administered. The term includes, but is not limited to,
273 gene mutations, characteristics of genes, and protein
274 expression.

275 (b) "Biomarker testing" means the analysis of a patient's
276 tissue, blood, or other biological specimen for the presence of
277 a biomarker. The term includes, but is not limited to, single-
278 analyte tests, multiplex panel tests, protein expression
279 analysis, and whole exome, whole genome, and whole transcriptome
280 sequencing.

281 (c) "Consensus statements" means statements developed by an
282 independent, multidisciplinary panel of experts using a
283 transparent methodology and reporting structure and with a
284 conflict of interest policy. These statements address specific
285 clinical circumstances, and the experts base these statements on
286 the best available evidence to optimize the outcomes of clinical
287 care.

288 (d) "Nationally recognized clinical practice guidelines"
289 means evidence-based clinical practice guidelines developed by
290 independent organizations or medical professional societies

8-01279-23

20231218__

291 using a transparent methodology and reporting structure and with
292 a conflict of interest policy. These guidelines establish
293 standards of care informed by a systematic review of evidence
294 and an assessment of the benefits and risks of alternative care
295 options and include recommendations intended to optimize patient
296 care.

297 (2) A health maintenance contract issued, delivered, or
298 renewed in this state on or after July 1, 2023, must provide
299 coverage for biomarker testing for diagnosis, treatment,
300 management, or ongoing monitoring of a subscriber's disease or
301 condition if use of the test is supported by medical and
302 scientific evidence. For purposes of coverage, all of the
303 following tests and circumstances for testing are deemed to be
304 supported by medical and scientific evidence:

305 (a) A test approved or cleared by the United States Food
306 and Drug Administration.

307 (b) Indicated tests for a drug approved by the United
308 States Food and Drug Administration.

309 (c) Warnings and precautions on the label for a drug
310 approved by the United States Food and Drug Administration.

311 (d) Tests approved under the Centers for Medicare and
312 Medicaid Services national coverage determination process or the
313 local coverage determination process of a Medicare
314 Administrative Contractor.

315 (e) Nationally recognized clinical practice guidelines and
316 consensus statements.

317 (3) Health maintenance organizations must ensure that
318 coverage of biomarker testing is provided in a manner that
319 limits disruptions in care, including, but not limited to,

8-01279-23

20231218__

320 coverage of biomarker testing for multiple biopsies or
321 biological specimen samples if needed.

322 (4) If utilization review for biomarker testing is
323 required, the health maintenance organization, utilization
324 review entity, or third party acting on behalf of the health
325 maintenance organization must approve or deny a prior
326 authorization request and notify the subscriber, the
327 subscriber's health care provider, and any entity requesting
328 authorization of the service within 72 hours after a nonurgent
329 request and within 24 hours after an urgent request.

330 (5) Health maintenance organizations must provide a clear,
331 readily accessible, and convenient process on their websites for
332 requesting an exception to the terms of a health maintenance
333 contract or for appealing an adverse utilization review
334 determination relating to biomarker testing services.

335 Section 5. This act shall take effect July 1, 2023.