

By Senator Calatayud

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1 A bill to be entitled
2 An act relating to coverage of biomarker testing;
3 amending s. 409.905, F.S.; defining terms; requiring
4 the Agency for Health Care Administration to provide
5 specified coverage of biomarker testing under the
6 Medicaid program; requiring managed care plans under
7 contract with the agency to provide coverage of
8 biomarker testing in a specified manner; requiring the
9 agency to provide a clear, readily accessible, and
10 convenient process for Medicaid recipients and
11 providers to request an exception to the coverage;
12 requiring that such process be made available in an
13 online format on the agency's website; providing
14 construction; creating ss. 627.64055 and 641.31708,
15 F.S.; defining terms; requiring that certain health
16 insurance policies and health maintenance contracts,
17 respectively, provide specified coverage of biomarker
18 testing; requiring that such coverage be provided in a
19 manner that limits disruption in care; requiring
20 insurers and health maintenance organizations,
21 respectively, to provide a clear, readily accessible,
22 and convenient process for covered individuals and
23 ordering or prescribing practitioners to request an
24 exception to the coverage; requiring that such process
25 be made available on the insurers' and health
26 maintenance organizations' respective websites;
27 providing construction; providing an effective date.

28
29 Be It Enacted by the Legislature of the State of Florida:

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

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law.

Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(13) BIOMARKER TESTING SERVICES.—

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

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

2. "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a

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59 biomarker. The term includes, but is not limited to, single-
60 analyte tests, multiplex panel tests, protein expression, and
61 whole exome, whole genome, and whole transcriptome sequencing
62 performed at a participating in-network laboratory facility that
63 the Centers for Medicare and Medicaid Services has either
64 certified or granted a waiver under the federal Clinical
65 Laboratory Improvement Amendments of 1988.

66 3. "Clinical utility" means that the test result provides
67 information used in the formulation of a treatment or in a
68 monitoring strategy that impacts a patient's outcome and informs
69 the clinical decision.

70 4. "Nationally recognized clinical practice guidelines"
71 means evidence-based clinical practice guidelines developed by
72 independent organizations or medical professional societies
73 using a transparent methodology and reporting structure and with
74 a conflict-of-interest policy. Clinical practice guidelines
75 establish standards of care informed by a systematic review of
76 evidence and an assessment of the benefits and costs of
77 alternative care options and include recommendations intended to
78 optimize patient care.

79 (b) The agency shall pay for biomarker testing for
80 diagnosis, treatment, management, and ongoing monitoring of a
81 recipient's disease or condition to guide treatment decisions
82 when such testing provides clinical utility to the recipient and
83 is demonstrated by medical and scientific evidence, including,
84 but not limited to, any of the following:

85 1. Labeled indications for a test approved or cleared by
86 the United States Food and Drug Administration (FDA) or
87 indicated tests for an FDA-approved drug.

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88 2. Centers for Medicare and Medicaid Services national
89 coverage determinations or Medicare Administrative Contractor
90 local coverage determinations.

91 3. Nationally recognized clinical practice guidelines.

92 (c) Managed care plans under contract with the agency to
93 deliver services to recipients shall provide biomarker testing
94 at the same scope, duration, and frequency as the Medicaid
95 program otherwise provides to enrollees.

96 (d) The agency shall provide a clear, readily accessible,
97 and convenient process for Medicaid recipients and providers to
98 request an exception to a coverage policy under the Medicaid
99 program or of managed care plans under contract with the agency
100 to provide services to enrollees. Such process must be made
101 available in an online format on the agency's website.

102 (e) This subsection may not be construed to require
103 coverage of biomarker testing for screening purposes.

104 Section 2. Section 627.64055, Florida Statutes, is created
105 to read:

106 627.64055 Coverage of biomarker testing.—

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

108 (a) "Biomarker" means a defined characteristic that is
109 measured as an indicator of normal biological processes,
110 pathogenic processes, or responses to an exposure or
111 intervention, including therapeutic interventions. The term
112 includes molecular, histologic, radiographic, and physiologic
113 characteristics but does not include an assessment of how a
114 patient feels, functions, or survives.

115 (b) "Biomarker testing" means the analysis of a patient's
116 tissue, blood, or other biospecimen for the presence of a

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117 biomarker. The term includes, but is not limited to, single-
118 analyte tests, multiplex panel tests, protein expression, and
119 whole exome, whole genome, and whole transcriptome sequencing
120 performed at a participating in-network laboratory facility that
121 the Centers for Medicare and Medicaid Services has either
122 certified or granted a waiver under the federal Clinical
123 Laboratory Improvement Amendments of 1988.

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

128 (d) "Nationally recognized clinical practice guidelines"
129 means evidence-based clinical practice guidelines developed by
130 independent organizations or medical professional societies
131 using a transparent methodology and reporting structure and with
132 a conflict-of-interest policy. Clinical practice guidelines
133 establish standards of care informed by a systematic review of
134 evidence and an assessment of the benefits and costs of
135 alternative care options and include recommendations intended to
136 optimize patient care.

137 (2) A health insurance policy issued, amended, delivered,
138 or renewed in this state on or after January 1, 2025, must
139 provide coverage for biomarker testing for the purposes of
140 diagnosis, treatment, appropriate management, and ongoing
141 monitoring of an insured's disease or condition to guide
142 treatment decisions when the testing provides clinical utility
143 to the patient as demonstrated by medical and scientific
144 evidence, including, but not limited to, any of the following:

145 (a) Labeled indications for a test approved or cleared by

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146 the United States Food and Drug Administration (FDA) or
147 indicated tests for an FDA-approved drug.

148 (b) Centers for Medicare and Medicaid Services national
149 coverage determinations or Medicare Administrative Contractor
150 local coverage determinations.

151 (c) Nationally recognized clinical practice guidelines.

152 (3) Coverage of biomarker testing must be provided in a
153 manner that limits disruptions in care, including the taking of
154 multiple biopsies or biospecimen samples.

155 (4) The insurer shall provide a clear, readily accessible,
156 and convenient process for insureds and ordering or prescribing
157 practitioners to request an exception to coverage of biomarker
158 testing in an insurance policy. Such process must be made
159 available in an online format on the insurer's website.

160 (5) This section may not be construed to require coverage
161 of biomarker testing for screening purposes.

162 Section 3. Section 641.31708, Florida Statutes, is created
163 to read:

164 641.31708 Coverage of biomarker testing.—

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

166 (a) "Biomarker" means a defined characteristic that is
167 measured as an indicator of normal biological processes,
168 pathogenic processes, or responses to an exposure or
169 intervention, including therapeutic interventions. The term
170 includes molecular, histologic, radiographic, and physiologic
171 characteristics but does not include an assessment of how a
172 patient feels, functions, or survives.

173 (b) "Biomarker testing" means the analysis of a patient's
174 tissue, blood, or other biospecimen for the presence of a

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175 biomarker. The term includes, but is not limited to, single-
176 analyte tests, multiplex panel tests, protein expression, and
177 whole exome, whole genome, and whole transcriptome sequencing
178 performed at a participating in-network laboratory facility that
179 the Centers for Medicare and Medicaid Services has either
180 certified or granted a waiver under the federal Clinical
181 Laboratory Improvement Amendments of 1988.

182 (c) "Clinical utility" means that the test result provides
183 information used in the formulation of a treatment or in a
184 monitoring strategy that impacts a patient's outcome and informs
185 the clinical decision.

186 (d) "Nationally recognized clinical practice guidelines"
187 means evidence-based clinical practice guidelines developed by
188 independent organizations or medical professional societies
189 using a transparent methodology and reporting structure and with
190 a conflict-of-interest policy. Clinical practice guidelines
191 establish standards of care informed by a systematic review of
192 evidence and an assessment of the benefits and costs of
193 alternative care options and include recommendations intended to
194 optimize patient care.

195 (2) A health maintenance contract issued, amended,
196 delivered, or renewed in this state on or after January 1, 2025,
197 must provide coverage for biomarker testing for the purposes of
198 diagnosis, treatment, appropriate management, and ongoing
199 monitoring of a subscriber's disease or condition to guide
200 treatment decisions when the testing provides clinical utility
201 to the patient as demonstrated by medical and scientific
202 evidence, including, but not limited to, any of the following:

203 (a) Labeled indications for a test approved or cleared by

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204 the United States Food and Drug Administration (FDA) or
205 indicated tests for an FDA-approved drug.

206 (b) Centers for Medicare and Medicaid Services national
207 coverage determinations or Medicare Administrative Contractor
208 local coverage determinations.

209 (c) Nationally recognized clinical practice guidelines.

210 (3) Coverage of biomarker testing must be provided in a
211 manner that limits disruptions in care, including the taking of
212 multiple biopsies or biospecimen samples.

213 (4) The health maintenance organization shall provide a
214 clear, readily accessible, and convenient process for
215 subscribers and ordering or prescribing practitioners to request
216 an exception to coverage of biomarker testing in a health
217 maintenance contract. Such process must be made available in an
218 online format on the health maintenance organization's website.

219 (5) This section may not be construed to require coverage
220 of biomarker testing for screening purposes.

221 Section 4. This act shall take effect July 1, 2024.