

HOUSE No. 4339

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, July 31, 2025.

The committee on Financial Services, to whom was referred the petition (accompanied by bill, House, No. 1227) of Meghan K. Kilcoyne and others relative to cancer patient access to biomarker testing to provide appropriate therapy, reports recommending that the accompanying bill (House, No. 4339) ought to pass.

For the committee,

JAMES M. MURPHY.

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The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Fourth General Court
(2025-2026)**

An Act relative to patient access to biomarker testing to provide appropriate therapy.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 32A of the General Laws is hereby amended by inserting after
2 section 17Z, the following section:-

3 Section 17AA. (a) As used in this section, the following words shall have the following
4 meanings:

5 “Biomarker” means a characteristic that is objectively measured and evaluated as an
6 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
7 specific therapeutic intervention, including known gene-drug interactions for medications being
8 considered for use or already being administered. Biomarkers include but are not limited to gene
9 mutations, characteristics of genes or protein expression.

10 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
11 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
12 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
13 transcriptome sequencing.

14 “Consensus statements” as used here are statements developed by an independent,
15 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
16 and with a conflict of interest policy. These statements are aimed at specific clinical
17 circumstances and base the statements on the best available evidence for the purpose of
18 optimizing the outcomes of clinical care.

19 “Nationally recognized clinical practice guidelines” as used here are evidence-based
20 clinical practice guidelines developed by independent organizations or medical professional
21 societies utilizing a transparent methodology and reporting structure and with a conflict of
22 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
23 review of evidence and an assessment of the benefits and risks of alternative care options and
24 include recommendations intended to optimize patient care.

25 (b) The commission shall provide to any active or retired employee of the commonwealth
26 who is insured under the group insurance commission coverage for biomarker testing as defined
27 in this section, pursuant to criteria established under subsection (c).

28 (c) Biomarker testing must be covered for the purposes of diagnosis, treatment,
29 appropriate management, or ongoing monitoring of an enrollee’s disease or condition when the
30 test is supported by medical and scientific evidence, including, but not limited to:

- 31 1. Labeled indications for an FDA-approved or -cleared test;
- 32 2. Indicated tests for an FDA-approved drug;
- 33 3. Warnings and precautions on FDA-approved drug labels;

34 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
35 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
36 Determinations; or

37 5. Nationally recognized clinical practice guidelines and consensus statements.

38 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
39 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

40 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
41 review organization subject to this section must approve or deny a prior authorization request or
42 appeal and notify the enrollee, the enrollee's health care provider and any entity requesting
43 authorization of the service within 72 hours. If additional delay would result in significant risk
44 to the insured's health or well-being, a carrier or a utilization review organization shall approve
45 or deny the request within 24 hours. If a response by a carrier or utilization review organization
46 is not received within the time required under this paragraph, said request or appeal shall be
47 deemed granted.

48 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
49 and convenient processes to request an exception to a coverage policy or an adverse utilization
50 review determination. The process shall be made readily accessible on the carrier's website.

51 SECTION 2. Chapter 118E of the General Laws is hereby amended by inserting after
52 section 10Z, the following section:-

53 Section 10AA. (a) As used in this section, the following words shall have the following
54 meanings:

55 “Biomarker” means a characteristic that is objectively measured and evaluated as an
56 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
57 specific therapeutic intervention, including known gene-drug interactions for medications being
58 considered for use or already being administered. Biomarkers include but are not limited to gene
59 mutations, characteristics of genes or protein expression.

60 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
61 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
62 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
63 transcriptome sequencing.

64 “Consensus statements” as used here are statements developed by an independent,
65 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
66 and with a conflict of interest policy. These statements are aimed at specific clinical
67 circumstances and base the statements on the best available evidence for the purpose of
68 optimizing the outcomes of clinical care.

69 “Nationally recognized clinical practice guidelines” as used here are evidence-based
70 clinical practice guidelines developed by independent organizations or medical professional
71 societies utilizing a transparent methodology and reporting structure and with a conflict of
72 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
73 review of evidence and an assessment of the benefits and risks of alternative care options and
74 include recommendations intended to optimize patient care.

75 (b) The division and its contracted health insurers, health plans, health maintenance
76 organizations, behavioral health management firms and third-party administrators under contract

77 to a Medicaid managed care organization or primary care clinician plan shall provide coverage
78 for biomarker testing as defined in this section, pursuant to criteria established under subsection
79 (c).

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

- 83 1. Labeled indications for an FDA-approved or -cleared test
- 84 2. Indicated tests for an FDA-approved drug;
- 85 3. Warnings and precautions on FDA-approved drug labels;
- 86 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
87 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
88 Determinations; or
- 89 5. Nationally recognized clinical practice guidelines and consensus statements.

90 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
91 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

92 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
93 review organization subject to this section must approve or deny a prior authorization request or
94 appeal and notify the enrollee, the enrollee's health care provider and any entity requesting
95 authorization of the service within 72 hours. If additional delay would result in significant risk
96 to the insured's health or well-being, a carrier or a utilization review organization shall approve
97 or deny the request within 24 hours. If a response by a carrier or utilization review organization

98 is not received within the time required under this paragraph, said request or appeal shall be
99 deemed granted.

100 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
101 and convenient processes to request an exception to a coverage policy or an adverse utilization
102 review determination. The process shall be made readily accessible on the carrier's website.

103 SECTION 3. Chapter 175 of the General Laws is hereby amended by inserting before
104 section 47CCC, the following section:-

105 Section 47AAA. (a) As used in this section, the following words shall have the following
106 meanings:

107 "Biomarker" means a characteristic that is objectively measured and evaluated as an
108 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
109 specific therapeutic intervention, including known gene-drug interactions for medications being
110 considered for use or already being administered. Biomarkers include but are not limited to gene
111 mutations, characteristics of genes or protein expression.

112 "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for
113 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
114 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
115 transcriptome sequencing.

116 "Consensus statements" as used here are statements developed by an independent,
117 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
118 and with a conflict of interest policy. These statements are aimed at specific clinical

119 circumstances and base the statements on the best available evidence for the purpose of
120 optimizing the outcomes of clinical care.

121 “Nationally recognized clinical practice guidelines” as used here are evidence-based
122 clinical practice guidelines developed by independent organizations or medical professional
123 societies utilizing a transparent methodology and reporting structure and with a conflict of
124 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
125 review of evidence and an assessment of the benefits and risks of alternative care options and
126 include recommendations intended to optimize patient care.

127 (b) Any blanket or general policy of insurance described in subdivision (A), (C), or (D)
128 of section one hundred and ten which is issued or subsequently renewed by agreement between
129 the insurer and the policyholder, within or without the commonwealth, during the period within
130 which this premium is effective, or any policy of accident or sickness insurance as described in
131 section one hundred and eight which provides hospital expense and surgical expense insurance
132 and which is delivered or issued for delivery or subsequently renewed by agreement between the
133 insurer and the policyholder in the commonwealth, during the period within which this provision
134 is effective, or any employers' health and welfare fund which provides hospital expense and
135 surgical expense benefits and which is issued or renewed to any person or group of persons in
136 the commonwealth, during the period within which this provision is effective, shall provide
137 benefits for residents of the commonwealth and all group members having a principal place of
138 employment in the commonwealth for biomarker testing as defined in this section, pursuant to
139 criteria established under subsection (c).

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

- 143 1. Labeled indications for an FDA-approved or -cleared test
- 144 2. Indicated tests for an FDA-approved drug;
- 145 3. Warnings and precautions on FDA-approved drug labels;
- 146 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
147 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
148 Determinations; or
- 149 5. Nationally recognized clinical practice guidelines and consensus statements.

150 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
151 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

152 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
153 review organization subject to this section must approve or deny a prior authorization request or
154 appeal and notify the enrollee, the enrollee's health care provider and any entity requesting
155 authorization of the service within 72 hours. If additional delay would result in significant risk
156 to the insured's health or well-being, a carrier or a utilization review organization shall approve
157 or deny the request within 24 hours. If a response by a carrier or utilization review organization
158 is not received within the time required under this paragraph, said request or appeal shall be
159 deemed granted.

160 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
161 and convenient processes to request an exception to a coverage policy or an adverse utilization
162 review determination. The process shall be made readily accessible on the carrier's website.

163 SECTION 4. Chapter 176A of the General Laws is hereby amended by inserting after
164 section 8DDD, the following section:-

165 Section 8EEE. (a) As used in this section, the following words shall have the following
166 meanings:

167 "Biomarker" means a characteristic that is objectively measured and evaluated as an
168 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
169 specific therapeutic intervention, including known gene-drug interactions for medications being
170 considered for use or already being administered. Biomarkers include but are not limited to gene
171 mutations, characteristics of genes or protein expression.

172 "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for
173 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
174 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
175 transcriptome, sequencing.

176 "Consensus statements" as used here are statements developed by an independent,
177 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
178 and with a conflict of interest policy. These statements are aimed at specific clinical
179 circumstances and base the statements on the best available evidence for the purpose of
180 optimizing the outcomes of clinical care.

181 “Nationally recognized clinical practice guidelines” as used here are evidence-based
182 clinical practice guidelines developed by independent organizations or medical professional
183 societies utilizing a transparent methodology and reporting structure and with a conflict of
184 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
185 review of evidence and an assessment of the benefits and risks of alternative care options and
186 include recommendations intended to optimize patient care.

187 (b) Any contract between a subscriber and the corporation under an individual or group
188 hospital service plan that is delivered, issued or renewed within the commonwealth shall provide
189 coverage for biomarker testing as defined in this section, pursuant to criteria established under
190 subsection (c).

191 (c) Biomarker testing must be covered for the purposes of diagnosis, treatment,
192 appropriate management, or ongoing monitoring of an enrollee’s disease or condition when the
193 test is supported by medical and scientific evidence, including, but not limited to:

- 194 1. Labeled indications for an FDA-approved or -cleared test
- 195 2. Indicated tests for an FDA-approved drug;
- 196 3. Warnings and precautions on FDA-approved drug labels;
- 197 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
198 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
199 Determinations; or
- 200 5. Nationally recognized clinical practice guidelines and consensus statements.

201 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
202 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

203 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
204 review organization subject to this section must approve or deny a prior authorization request or
205 appeal and notify the enrollee, the enrollee's health care provider and any entity requesting
206 authorization of the service within 72 hours. If additional delay would result in significant risk
207 to the insured's health or well-being, a carrier or a utilization review organization shall approve
208 or deny the request within 24 hours. If a response by a carrier or utilization review organization
209 is not received within the time required under this paragraph, said request or appeal shall be
210 deemed granted.

211 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
212 and convenient processes to request an exception to a coverage policy or an adverse utilization
213 review determination. The process shall be made readily accessible on the carrier's website.

214 SECTION 5. Chapter 176B of the General Laws is hereby amended by inserting after
215 section 4DDD, the following section:-

216 Section 4EEE. (a) As used in this section, the following words shall have the following
217 meanings:

218 "Biomarker" means a characteristic that is objectively measured and evaluated as an
219 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
220 specific therapeutic intervention, including known gene-drug interactions for medications being
221 considered for use or already being administered. Biomarkers include but are not limited to gene
222 mutations, characteristics of genes or protein expression.

223 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
224 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
225 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
226 transcriptome sequencing.

227 “Consensus statements” as used here are statements developed by an independent,
228 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
229 and with a conflict of interest policy. These statements are aimed at specific clinical
230 circumstances and base the statements on the best available evidence for the purpose of
231 optimizing the outcomes of clinical care.

232 “Nationally recognized clinical practice guidelines” as used here are evidence-based
233 clinical practice guidelines developed by independent organizations or medical professional
234 societies utilizing a transparent methodology and reporting structure and with a conflict of
235 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
236 review of evidence and an assessment of the benefits and risks of alternative care options and
237 include recommendations intended to optimize patient care.

238 (b) Any subscription certificate under an individual or group medical service agreement
239 delivered, issued or renewed within the commonwealth shall provide coverage for biomarker
240 testing as defined in this section, pursuant to criteria established under subsection (c).

241 (c) Biomarker testing must be covered for the purposes of diagnosis, treatment,
242 appropriate management, or ongoing monitoring of an enrollee’s disease or condition when the
243 test is supported by medical and scientific evidence, including, but not limited to:

244 1. Labeled indications for an FDA-approved or -cleared test

- 245 2. Indicated tests for an FDA-approved drug;
- 246 3. Warnings and precautions on FDA-approved drug labels;
- 247 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
248 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
249 Determinations; or

250 5. Nationally recognized clinical practice guidelines and consensus statements.

251 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
252 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

253 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
254 review organization subject to this section must approve or deny a prior authorization request or
255 appeal and notify the enrollee, the enrollee’s health care provider and any entity requesting
256 authorization of the service within 72 hours. If additional delay would result in significant risk
257 to the insured’s health or well-being, a carrier or a utilization review organization shall approve
258 or deny the request within 24 hours. If a response by a carrier or utilization review organization
259 is not received within the time required under this paragraph, said request or appeal shall be
260 deemed granted.

261 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
262 and convenient processes to request an exception to a coverage policy or an adverse utilization
263 review determination. The process shall be made readily accessible on the carrier’s website.

264 SECTION 6. Chapter 176G of the General Laws is hereby amended by inserting after
265 section 4VV, as so appearing, the following section:-

266 Section 4WW. (a) As used in this section, the following words shall have the following
267 meanings:

268 “Biomarker” means a characteristic that is objectively measured and evaluated as an
269 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
270 specific therapeutic intervention, including known gene-drug interactions for medications being
271 considered for use or already being administered. Biomarkers include but are not limited to gene
272 mutations, characteristics of genes or protein expression.

273 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
274 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
275 multi-plex panel tests, protein expression, and whole exome, whole genome, and whole
276 transcriptome sequencing.

277 “Consensus statements” as used here are statements developed by an independent,
278 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure
279 and with a conflict of interest policy. These statements are aimed at specific clinical
280 circumstances and base the statements on the best available evidence for the purpose of
281 optimizing the outcomes of clinical care.

282 “Nationally recognized clinical practice guidelines” as used here are evidence-based
283 clinical practice guidelines developed by independent organizations or medical professional
284 societies utilizing a transparent methodology and reporting structure and with a conflict of
285 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
286 review of evidence and an assessment of the benefits and risks of alternative care options and
287 include recommendations intended to optimize patient care.

288 (b) Any individual or group health maintenance contract that is issued or renewed within
289 or without the commonwealth shall provide coverage for biomarker testing as defined in this
290 section, pursuant to criteria established under subsection (c).

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

- 294 1. Labeled indications for an FDA-approved or -cleared test
- 295 2. Indicated tests for an FDA-approved drug;
- 296 3. Warnings and precautions on FDA-approved drug labels;
- 297 4. Centers for Medicare and Medicaid Services (CMS) National Coverage
298 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
299 Determinations; or
- 300 5. Nationally recognized clinical practice guidelines and consensus statements.

301 (d) coverage as defined in subsection (c) of this section shall be provided in a manner that
302 limits disruptions in care including the need for multiple biopsies or biospecimen samples.

303 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
304 review organization subject to this section must approve or deny a prior authorization request or
305 appeal and notify the enrollee, the enrollee's health care provider and any entity requesting
306 authorization of the service within 72 hours. If additional delay would result in significant risk
307 to the insured's health or well-being, a carrier or a utilization review organization shall approve
308 or deny the request within 24 hours. If a response by a carrier or utilization review organization

309 is not received within the time required under this paragraph, said request or appeal shall be
310 deemed granted.

311 (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,
312 and convenient processes to request an exception to a coverage policy or an adverse utilization
313 review determination. The process shall be made readily accessible on the carrier's website.