

**HOUSE . . . . . No.**

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**The Commonwealth of Massachusetts**

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PRESENTED BY:

***Meghan K. Kilcoyne***

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*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

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

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PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Meghan K. Kilcoyne</i>	<i>12th Worcester</i>	<i>1/16/2025</i>

**HOUSE . . . . . No.**

[Pin Slip]

**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 17Q, the following section:-

3 Section 17R. (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 10L, the following section:-

53 Section 10M. (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 after  
104 section 47KK, the following section:-

105 Section 47LL. (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) An individual policy of accident and sickness insurance issued under section 108 that  
128 provides benefits for hospital expenses and surgical expenses and any group blanket policy of  
129 accident and sickness insurance issued under section 110 that provides benefits for hospital  
130 expenses and surgical expenses delivered, issued or renewed by agreement between the insurer  
131 and the policyholder, within or outside the commonwealth, shall provide benefits for residents of  
132 the commonwealth and all group members having a principal place of employment in the  
133 commonwealth for biomarker testing as defined in this section, pursuant to criteria established  
134 under subsection (c).

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

- 138 1. Labeled indications for an FDA-approved or -cleared test
- 139 2. Indicated tests for an FDA-approved drug;



- 140           3.       Warnings and precautions on FDA-approved drug labels;
- 141           4.       Centers for Medicare and Medicaid Services (CMS) National Coverage
- 142    Determinations or any Medicare Administrative Contractor (MAC) Local Coverage
- 143    Determinations; or
- 144           5.       Nationally recognized clinical practice guidelines and consensus statements.

145           (d) coverage as defined in subsection (c) of this section shall be provided in a manner that

146    limits disruptions in care including the need for multiple biopsies or biospecimen samples.

147           (e) In the case of coverage which requires prior authorization, a carrier or a utilization

148    review organization subject to this section must approve or deny a prior authorization request or

149    appeal and notify the enrollee, the enrollee's health care provider and any entity requesting

150    authorization of the service within 72 hours. If additional delay would result in significant risk

151    to the insured's health or well-being, a carrier or a utilization review organization shall approve

152    or deny the request within 24 hours. If a response by a carrier or utilization review organization

153    is not received within the time required under this paragraph, said request or appeal shall be

154    deemed granted.

155           (f) The patient and prescribing practitioner shall have access to a clear, readily accessible,

156    and convenient processes to request an exception to a coverage policy or an adverse utilization

157    review determination. The process shall be made readily accessible on the carrier's website.

158           SECTION 4. Chapter 176A of the General Laws is hereby amended by inserting after

159    section 8MM, the following section:-

160 Section 8NN. (a) As used in this section, the following words shall have the following  
161 meanings:

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

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

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

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

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

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

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

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

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

203 or deny the request within 24 hours. If a response by a carrier or utilization review organization  
204 is not received within the time required under this paragraph, said request or appeal shall be  
205 deemed granted.

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

209 SECTION 5. Chapter 176B of the General Laws is hereby amended by inserting after  
210 section 4MM, the following section:-

211 Section 4NN. (a) As used in this section, the following words shall have the following  
212 meanings:

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

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

222 "Consensus statements" as used here are statements developed by an independent,  
223 multidisciplinary panel of experts utilizing a transparent methodology and reporting structure

224 and with a conflict of interest policy. These statements are aimed at specific clinical  
225 circumstances and base the statements on the best available evidence for the purpose of  
226 optimizing the outcomes of clinical care.

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

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

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

- 239 1. Labeled indications for an FDA-approved or -cleared test
- 240 2. Indicated tests for an FDA-approved drug;
- 241 3. Warnings and precautions on FDA-approved drug labels;
- 242 4. Centers for Medicare and Medicaid Services (CMS) National Coverage  
243 Determinations or any Medicare Administrative Contractor (MAC) Local Coverage  
244 Determinations; or

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

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

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

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

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

261 Section 4FF. (a) As used in this section, the following words shall have the following  
262 meanings:

263 "Biomarker" means a characteristic that is objectively measured and evaluated as an  
264 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a  
265 specific therapeutic intervention, including known gene-drug interactions for medications being

266 considered for use or already being administered. Biomarkers include but are not limited to gene  
267 mutations, characteristics of genes or protein expression.

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

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

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

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

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

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

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

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



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