

SENATE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Jacob R. Oliveira

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.

PETITION OF:

NAME:

Jacob R. Oliveira

DISTRICT/ADDRESS:

Hampden, Hampshire and Worcester

SENATE No.

[Pin Slip]

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. 689 OF 2023-2024.]

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.