

SENATE No. 689

The Commonwealth of Massachusetts

PRESENTED BY:

Susan L. Moran

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: | DISTRICT/ADDRESS: | |
|---------------------------------|--|------------------|
| <i>Susan L. Moran</i> | <i>Plymouth and Barnstable</i> | |
| <i>Jack Patrick Lewis</i> | <i>7th Middlesex</i> | <i>1/30/2023</i> |
| <i>Michael O. Moore</i> | <i>Second Worcester</i> | <i>2/2/2023</i> |
| <i>William J. Driscoll, Jr.</i> | <i>7th Norfolk</i> | <i>2/6/2023</i> |
| <i>John J. Cronin</i> | <i>Worcester and Middlesex</i> | <i>2/8/2023</i> |
| <i>John C. Velis</i> | <i>Hampden and Hampshire</i> | <i>2/8/2023</i> |
| <i>Jason M. Lewis</i> | <i>Fifth Middlesex</i> | <i>2/8/2023</i> |
| <i>Patrick M. O'Connor</i> | <i>First Plymouth and Norfolk</i> | <i>2/8/2023</i> |
| <i>Joanne M. Comerford</i> | <i>Hampshire, Franklin and Worcester</i> | <i>2/10/2023</i> |
| <i>Walter F. Timilty</i> | <i>Norfolk, Plymouth and Bristol</i> | <i>2/10/2023</i> |
| <i>Thomas M. Stanley</i> | <i>9th Middlesex</i> | <i>2/10/2023</i> |
| <i>Anne M. Gobi</i> | <i>Worcester and Hampshire</i> | <i>2/10/2023</i> |
| <i>Michael D. Brady</i> | <i>Second Plymouth and Norfolk</i> | <i>2/10/2023</i> |
| <i>Carmine Lawrence Gentile</i> | <i>13th Middlesex</i> | <i>2/15/2023</i> |
| <i>Aaron L. Saunders</i> | <i>7th Hampden</i> | <i>2/28/2023</i> |

SENATE No. 689

By Ms. Moran, a petition (accompanied by bill, Senate, No. 689) of Susan L. Moran, Jack Patrick Lewis, Michael O. Moore, William J. Driscoll, Jr. and other members of the General Court for legislation relative to patient access to biomarker testing to provide appropriate therapy. Financial Services.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Third General Court
(2023-2024)**

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 17R, the following section:-

3 Section 17S. (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. Biomarkers include but are not limited to gene mutations or
8 protein expression.

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

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

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

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

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

29 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
30 FDA-approved drug;

31 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
32 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;

33 or

34 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

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

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

47 SECTION 2. Chapter 118E of the General Laws is hereby amended by inserting after
48 section 10N, the following section:-

49 Section 10O. (a) As used in this section, the following words shall have the following
50 meanings:

51 "Biomarker" means a characteristic that is objectively measured and evaluated as an
52 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
53 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or
54 protein expression.

55 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
56 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
57 multi-plex panel tests, and whole genome sequencing.

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

63 “Nationally recognized clinical practice guidelines” as used here are evidence-based
64 clinical practice guidelines developed by independent organizations or medical professional
65 societies utilizing a transparent methodology and reporting structure and with a conflict of
66 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
67 review of evidence and an assessment of the benefits and costs of alternative care options and
68 include recommendations intended to optimize patient care.

69 (b) The division and its contracted health insurers, health plans, health maintenance
70 organizations, behavioral health management firms and third-party administrators under contract
71 to a Medicaid managed care organization or primary care clinician plan shall provide coverage
72 for biomarker testing as defined in this section, pursuant to criteria established under subsection
73 (c).

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

77 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
78 FDA-approved drug;

79 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
80 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;
81 or

82 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

85 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
86 review organization subject to this section must approve or deny a prior authorization request or
87 appeal and notify the enrollee and the enrollee's health care provider within 72 hours. If
88 additional delay would result in significant risk to the insured's health or well-being, a carrier or
89 a utilization review organization shall approve or deny the request within 24 hours. If a response
90 by a carrier or utilization review organization is not received within the time required under this
91 paragraph, said request or appeal shall be deemed granted.

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

95 SECTION 3. Chapter 175 of the General Laws is hereby amended by inserting after
96 section 47PP, the following section:-

97 Section 47QQ. (a) As used in this section, the following words shall have the following
98 meanings:

99 “Biomarker” means a characteristic that is objectively measured and evaluated as an
100 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
101 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or
102 protein expression.

103 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
104 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
105 multi-plex panel tests, and whole genome sequencing.

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

111 “Nationally recognized clinical practice guidelines” as used here are evidence-based
112 clinical practice guidelines developed by independent organizations or medical professional
113 societies utilizing a transparent methodology and reporting structure and with a conflict of
114 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
115 review of evidence and an assessment of the benefits and costs of alternative care options and
116 include recommendations intended to optimize patient care.

117 (b) An individual policy of accident and sickness insurance issued under section 108 that
118 provides benefits for hospital expenses and surgical expenses and any group blanket policy of

119 accident and sickness insurance issued under section 110 that provides benefits for hospital
120 expenses and surgical expenses delivered, issued or renewed by agreement between the insurer
121 and the policyholder, within or outside the commonwealth, shall provide benefits for residents of
122 the commonwealth and all group members having a principal place of employment in the
123 commonwealth for biomarker testing as defined in this section, pursuant to criteria established
124 under subsection (c).

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

128 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
129 FDA-approved drug;

130 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
131 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;
132 or

133 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

136 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
137 review organization subject to this section must approve or deny a prior authorization request or
138 appeal and notify the enrollee and the enrollee's health care provider within 72 hours. If
139 additional delay would result in significant risk to the insured's health or well-being, a carrier or

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

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

146 SECTION 4. Chapter 176A of the General Laws is hereby amended by inserting after
147 section 8QQ, the following section:-

148 Section 8RR. (a) As used in this section, the following words shall have the following
149 meanings:

150 "Biomarker" means a characteristic that is objectively measured and evaluated as an
151 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
152 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or
153 protein expression.

154 "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for
155 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
156 multi-plex panel tests, and whole genome sequencing.

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

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

162 “Nationally recognized clinical practice guidelines” as used here are evidence-based
163 clinical practice guidelines developed by independent organizations or medical professional
164 societies utilizing a transparent methodology and reporting structure and with a conflict of
165 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
166 review of evidence and an assessment of the benefits and costs of alternative care options and
167 include recommendations intended to optimize patient care.

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

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

175 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
176 FDA-approved drug;

177 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
178 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;
179 or

180 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

183 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
184 review organization subject to this section must approve or deny a prior authorization request or
185 appeal and notify the enrollee and the enrollee's health care provider within 72 hours. If
186 additional delay would result in significant risk to the insured's health or well-being, a carrier or
187 a utilization review organization shall approve or deny the request within 24 hours. If a response
188 by a carrier or utilization review organization is not received within the time required under this
189 paragraph, said request or appeal shall be deemed granted.

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

193 SECTION 5. Chapter 176B of the General Laws is hereby amended by inserting after
194 section 4QQ, the following section:-

195 Section 4RR. (a) As used in this section, the following words shall have the following
196 meanings:

197 "Biomarker" means a characteristic that is objectively measured and evaluated as an
198 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
199 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or
200 protein expression.

201 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
202 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
203 multi-plex panel tests, and whole genome sequencing.

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

209 “Nationally recognized clinical practice guidelines” as used here are evidence-based
210 clinical practice guidelines developed by independent organizations or medical professional
211 societies utilizing a transparent methodology and reporting structure and with a conflict of
212 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
213 review of evidence and an assessment of the benefits and costs of alternative care options and
214 include recommendations intended to optimize patient care.

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

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

221 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
222 FDA-approved drug;

223 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
224 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;
225 or

226 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

229 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
230 review organization subject to this section must approve or deny a prior authorization request or
231 appeal and notify the enrollee and the enrollee's health care provider within 72 hours. If
232 additional delay would result in significant risk to the insured's health or well-being, a carrier or
233 a utilization review organization shall approve or deny the request within 24 hours. If a response
234 by a carrier or utilization review organization is not received within the time required under this
235 paragraph, said request or appeal shall be deemed granted.

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

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

241 Section 4JJ. (a) As used in this section, the following words shall have the following
242 meanings:

243 “Biomarker” means a characteristic that is objectively measured and evaluated as an
244 indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a
245 specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or
246 protein expression.

247 “Biomarker testing” is the analysis of a patient’s tissue, blood, or other biospecimen for
248 the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests,
249 multi-plex panel tests, and whole genome sequencing.

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

255 “Nationally recognized clinical practice guidelines” as used here are evidence-based
256 clinical practice guidelines developed by independent organizations or medical professional
257 societies utilizing a transparent methodology and reporting structure and with a conflict of
258 interest policy. Clinical practice guidelines establish standards of care informed by a systematic
259 review of evidence and an assessment of the benefits and costs of alternative care options and
260 include recommendations intended to optimize patient care.

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

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

267 (1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an
268 FDA-approved drug;

269 (2) Centers for Medicare and Medicaid Services (CMS) National Coverage
270 Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations;
271 or

272 (3) Nationally recognized clinical practice guidelines and consensus statements.

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

275 (e) In the case of coverage which requires prior authorization, a carrier or a utilization
276 review organization subject to this section must approve or deny a prior authorization request or
277 appeal and notify the enrollee and the enrollee's health care provider within 72 hours. If
278 additional delay would result in significant risk to the insured's health or well-being, a carrier or
279 a utilization review organization shall approve or deny the request within 24 hours. If a response
280 by a carrier or utilization review organization is not received within the time required under this
281 paragraph, said request or appeal shall be deemed granted.

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