

**SENATE . . . . . No.**

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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>

**SENATE . . . . . No.**

[Pin Slip]

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.