SENATE DOCKET, NO. 1687 FILED ON: 1/19/2023

# SENATE . . . . . No.

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: | |
|---|---|---|
| *Susan L. Moran* | *Plymouth and Barnstable* | |
| *Jack Patrick Lewis* | *7th Middlesex* | *1/30/2023* |
| *Michael O. Moore* | *Second Worcester* | *2/2/2023* |

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# 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:*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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