HOUSE DOCKET, NO. 2335 FILED ON: 1/16/2025

HOUSE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Meghan K. Kilcoyne

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:	DATE ADDED:
Meghan K. Kilcoyne	*12th Worcester*	*1/16/2025*

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HOUSE . . . . . No.

[Pin Slip]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

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

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

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

Section 17R. (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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome 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 risks 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;

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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 10L, the following section:-

Section 10M. (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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome 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 risks 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

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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 47KK, the following section:-

Section 47LL. (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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome 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 risks 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

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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 8MM, the following section:-

Section 8NN. (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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome, 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 risks 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

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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 4MM, the following section:-

Section 4NN. (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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome 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 risks 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

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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 4EE, as so appearing, the following section:-

Section 4FF. (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, including known gene-drug interactions for medications being

considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes 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, protein expression, and whole exome, whole genome, and whole transcriptome 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 risks 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

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

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

5. 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, the enrollee's health care provider and any entity requesting authorization of the service 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.