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Legislative Document

No. 107

H.P. 72

House of Representatives, January 8, 2025

An Act to Require Health Insurance Coverage for Biomarker Testing

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Robert B. Hunt".

ROBERT B. HUNT
Clerk

Presented by Representative ZAGER of Portland.
Cosponsored by Senator BENNETT of Oxford and
Representatives: ARATA of New Gloucester, CLUCHEY of Bowdoinham, JAVNER of
Chester, MATHIESON of Kittery, Senators: BAILEY of York, CYRWAY of Kennebec.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA §3174-PPP** is enacted to read:

3 **§3174-PPP. Biomarker testing coverage**

4 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
5 following terms have the following meanings.

6 A. "Biomarker" means a characteristic that is objectively measured and evaluated as
7 an indicator of a normal biological process, pathogenic process or pharmacologic
8 response to a specific therapeutic intervention, including a known gene-drug
9 interaction for a medication being considered for use or already being administered.
10 "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or
11 protein expression.

12 B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological
13 specimen for the presence of a biomarker. "Biomarker testing" includes but is not
14 limited to a single analyte test, multiplex panel test, protein expression and whole
15 exome, whole genome and whole transcriptome sequencing.

16 C. "Consensus statement" means a statement:

17 (1) Developed by an independent, multidisciplinary panel of experts using a
18 transparent methodology and reporting structure and with a conflict of interest
19 policy;

20 (2) Aimed at specific clinical circumstances; and

21 (3) Based on the best available evidence for the purpose of optimizing the
22 outcomes of clinical care.

23 D. "Nationally recognized clinical practice guideline" means an evidence-based
24 clinical practice guideline:

25 (1) Developed by an independent organization or medical professional society
26 using a transparent methodology and reporting structure and with a conflict of
27 interest policy;

28 (2) That establishes a standard of care informed by a systematic review of evidence
29 and an assessment of the benefits and risks of alternative care options; and

30 (3) That includes recommendations intended to optimize patient care.

31 **2. Required coverage.** The department shall provide coverage for biomarker testing
32 for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring
33 of a disease or condition of a MaineCare member when the test is supported by medical
34 and scientific evidence, including, but not limited to:

35 A. A labeled indication for a test approved or cleared by the federal Food and Drug
36 Administration;

37 B. An indicated test for a drug approved by the federal Food and Drug Administration;

38 C. A warning or precaution on a label of a drug approved by the federal Food and
39 Drug Administration;

1 D. A federal Department of Health and Human Services, Centers for Medicare and
2 Medicaid Services national coverage determination or Medicare administrative
3 contractor local coverage determination; or

4 E. A nationally recognized clinical practice guideline or consensus statement.

5 Coverage described in this subsection must provide for the delivery of biomarker testing
6 services in a manner that limits disruptions in care, including the need for multiple biopsies
7 or biological specimen samples.

8 **Sec. 2. 24 MRSA §2317-B, sub-§9-A** is enacted to read:

9 **9-A. Title 24-A, sections 2745-H, 2837-I and 4237-B.** Biomarker testing coverage,
10 Title 24-A, sections 2745-H, 2837-I and 4237-B;

11 **Sec. 3. 24-A MRSA §2745-H** is enacted to read:

12 **§2745-H. Biomarker testing insurance coverage**

13 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
14 following terms have the following meanings.

15 A. "Biomarker" means a characteristic that is objectively measured and evaluated as
16 an indicator of a normal biological process, pathogenic process or pharmacologic
17 response to a specific therapeutic intervention, including a known gene-drug
18 interaction for a medication being considered for use or already being administered.
19 "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or
20 protein expression.

21 B. "Biomarker testing" means the analysis of a patient's tissue, blood or other
22 biological specimen for the presence of a biomarker. "Biomarker testing" includes but
23 is not limited to a single analyte test, multiplex panel test, protein expression and whole
24 exome, whole genome and whole transcriptome sequencing.

25 C. "Consensus statement" means a statement:

26 (1) Developed by an independent, multidisciplinary panel of experts using a
27 transparent methodology and reporting structure and with a conflict of interest
28 policy;

29 (2) Aimed at specific clinical circumstances; and

30 (3) Based on the best available evidence for the purpose of optimizing the
31 outcomes of clinical care.

32 D. "Nationally recognized clinical practice guideline" means an evidence-based
33 clinical practice guideline:

34 (1) Developed by an independent organization or medical professional society
35 using a transparent methodology and reporting structure and with a conflict of
36 interest policy;

37 (2) That establishes a standard of care informed by a systematic review of evidence
38 and an assessment of the benefits and risks of alternative care options; and

39 (3) That includes recommendations intended to optimize patient care.

1 **2. Required coverage.** An individual health insurance policy must provide coverage
2 for biomarker testing for the purposes of diagnosis, treatment, appropriate management or
3 ongoing monitoring of a disease or condition of a person covered by the policy when the
4 test is supported by medical and scientific evidence, including, but not limited to:

5 A. A labeled indication for a test approved or cleared by the federal Food and Drug
6 Administration;

7 B. An indicated test for a drug approved by the federal Food and Drug Administration;

8 C. A warning or precaution on a label of a drug approved by the federal Food and
9 Drug Administration;

10 D. A federal Department of Health and Human Services, Centers for Medicare and
11 Medicaid Services national coverage determination or Medicare administrative
12 contractor local coverage determination; or

13 E. A nationally recognized clinical practice guideline or consensus statement.

14 A policy described in this subsection must provide for coverage in a manner that limits
15 disruptions in care, including the need for multiple biopsies or biological specimen
16 samples.

17 **3. Utilization review.** If an individual insurance policy contains a provision whereby
18 in nonemergency cases the insured is required to be prospectively evaluated through a
19 prehospital admission certification, a preinpatient service eligibility program or any similar
20 preutilization review or screening procedure prior to biomarker testing, the utilization
21 review entity or any 3rd party acting on behalf of an organization or entity subject to this
22 section must approve or deny a prior authorization request and notify the person covered
23 by the policy, the person's health care provider and any entity requesting authorization of
24 the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

25 **Sec. 4. 24-A MRSA §2837-I** is enacted to read:

26 **§2837-I. Biomarker testing insurance coverage**

27 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
28 following terms have the following meanings.

29 A. "Biomarker" means a characteristic that is objectively measured and evaluated as
30 an indicator of a normal biological process, pathogenic process or pharmacologic
31 response to a specific therapeutic intervention, including a known gene-drug
32 interaction for a medication being considered for use or already being administered.
33 "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or
34 protein expression.

35 B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological
36 specimen for the presence of a biomarker. "Biomarker testing" includes but is not
37 limited to a single analyte test, multiplex panel test, protein expression and whole
38 exome, whole genome and whole transcriptome sequencing.

39 C. "Consensus statement" means a statement:

40 (1) Developed by an independent, multidisciplinary panel of experts using a
41 transparent methodology and reporting structure and with a conflict of interest
42 policy;

- 1 (2) Aimed at specific clinical circumstances; and
2 (3) Based on the best available evidence for the purpose of optimizing the
3 outcomes of clinical care.

4 D. "Nationally recognized clinical practice guideline" means an evidence-based
5 clinical practice guideline:

6 (1) Developed by an independent organization or medical professional society
7 using a transparent methodology and reporting structure and with a conflict of
8 interest policy;

9 (2) That establishes a standard of care informed by a systematic review of evidence
10 and an assessment of the benefits and risks of alternative care options; and

11 (3) That includes recommendations intended to optimize patient care.

12 **2. Required coverage.** A group health insurance policy must provide coverage for
13 biomarker testing for the purposes of diagnosis, treatment, appropriate management or
14 ongoing monitoring of a disease or condition of an insured person or subscriber covered by
15 that policy when the test is supported by medical and scientific evidence, including, but not
16 limited to:

17 A. A labeled indication for a test approved or cleared by the federal Food and Drug
18 Administration;

19 B. An indicated test for a drug approved by the federal Food and Drug Administration;

20 C. A warning or precaution on a label of a drug approved by the federal Food and
21 Drug Administration;

22 D. A federal Department of Health and Human Services, Centers for Medicare and
23 Medicaid Services national coverage determination or Medicare administrative
24 contractor local coverage determination; or

25 E. A nationally recognized clinical practice guideline or consensus statement.

26 A policy described in this subsection must provide for coverage in a manner that limits
27 disruptions in care, including the need for multiple biopsies or biological specimen
28 samples.

29 **3. Utilization review.** If a group insurance policy contains a provision whereby in
30 nonemergency cases the insured is required to be prospectively evaluated through a
31 prehospital admission certification, a preinpatient service eligibility program or any similar
32 preutilization review or screening procedure prior to biomarker testing, the utilization
33 review entity or any 3rd party acting on behalf of an organization or entity subject to this
34 section must approve or deny a prior authorization request and notify the insured person or
35 subscriber covered by that policy, the insured person's or subscriber's health care provider
36 and any entity requesting authorization of the service within 72 hours for nonurgent
37 requests or within 24 hours for urgent requests.

38 **Sec. 5. 24-A MRSA §4237-B** is enacted to read:

39 **§4237-B. Biomarker testing insurance coverage**

40 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
41 following terms have the following meanings.

1 A. "Biomarker" means a characteristic that is objectively measured and evaluated as
2 an indicator of a normal biological process, pathogenic process or pharmacologic
3 response to a specific therapeutic intervention, including a known gene-drug
4 interaction for a medication being considered for use or already being administered.
5 "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or
6 protein expression.

7 B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological
8 specimen for the presence of a biomarker. "Biomarker testing" includes but is not
9 limited to a single analyte test, multiplex panel test, protein expression and whole
10 exome, whole genome and whole transcriptome sequencing.

11 C. "Consensus statement" means a statement:

12 (1) Developed by an independent, multidisciplinary panel of experts using a
13 transparent methodology and reporting structure and with a conflict of interest
14 policy;

15 (2) Aimed at specific clinical circumstances; and

16 (3) Based on the best available evidence for the purpose of optimizing the
17 outcomes of clinical care.

18 D. "Nationally recognized clinical practice guideline" means an evidence-based
19 clinical practice guideline:

20 (1) Developed by an independent organization or medical professional society
21 using a transparent methodology and reporting structure and with a conflict of
22 interest policy;

23 (2) That establishes a standard of care informed by a systematic review of evidence
24 and an assessment of the benefits and risks of alternative care options; and

25 (3) That includes recommendations intended to optimize patient care.

26 **2. Required coverage.** Individual or group coverage subject to this chapter must
27 provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate
28 management or ongoing monitoring of a disease or condition of an insured person, member
29 or subscriber covered by that policy when the test is supported by medical and scientific
30 evidence, including, but not limited to:

31 A. A labeled indication for a test approved or cleared by the federal Food and Drug
32 Administration;

33 B. An indicated test for a drug approved by the federal Food and Drug Administration;

34 C. A warning or precaution on a label of a drug approved by the federal Food and
35 Drug Administration;

36 D. A federal Department of Health and Human Services, Centers for Medicare and
37 Medicaid Services national coverage determination or Medicare administrative
38 contractor local coverage determination; or

39 E. A nationally recognized clinical practice guideline or consensus statement.

1 A policy described in this subsection must provide for coverage in a manner that limits
2 disruptions in care, including the need for multiple biopsies or biological specimen
3 samples.

4 **3. Utilization review.** If a group insurance policy contains a provision whereby in
5 nonemergency cases the insured is required to be prospectively evaluated through a
6 prehospital admission certification, a preinpatient service eligibility program or any similar
7 preutilization review or screening procedure prior to biomarker testing, the utilization
8 review entity or any 3rd party acting on behalf of an organization or entity subject to this
9 section must approve or deny a prior authorization request and notify the insured person or
10 subscriber covered by that policy, the insured person's or subscriber's health care provider
11 and any entity requesting authorization of the service within 72 hours for nonurgent
12 requests or within 24 hours for urgent requests.

13 **Sec. 6. Application.** The requirements of the Maine Revised Statutes, Title 22,
14 section 3174-PPP and Title 24-A, sections 2745-H, 2837-I and 4237-B apply to a policy,
15 contract, certificate or other instrument of insurance coverage that takes effect or is renewed
16 on or after January 1, 2026.

17 SUMMARY

18 This bill requires insurance coverage, including coverage in the MaineCare program,
19 for biomarker testing.