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Legislative Document

No. 1577

H.P. 1022

House of Representatives, April 11, 2023

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, CYRWAY of Albion, JAVNER of Chester,
PERRY of Calais, SWALLOW of Houlton, Senators: BAILEY of York, RENY of Lincoln.

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

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

3 **§3174-KKK. 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 developed by an independent organization or medical
25 professional society using a transparent methodology and reporting structure and with
26 a conflict of interest policy that establishes a standard of care informed by a systematic
27 review of evidence and an assessment of the benefits and risks of alternative care
28 options and includes recommendations intended to optimize patient care.

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

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

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

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

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

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

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

4 **Sec. 2. 24 MRSA §2320-H** is enacted to read:

5 **§2320-H. Biomarker testing insurance coverage**

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

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

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

18 C. "Consensus statement" means a statement:

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

22 (2) Aimed at specific clinical circumstances; and

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

25 D. "Nationally recognized clinical practice guideline" means an evidence-based
26 clinical practice guideline developed by an independent organization or medical
27 professional society using a transparent methodology and reporting structure and with
28 a conflict of interest policy that establishes a standard of care informed by a systematic
29 review of evidence and an assessment of the benefits and risks of alternative care
30 options and includes recommendations intended to optimize patient care.

31 **2. Required coverage.** An individual and group nonprofit hospital and medical
32 services plan contract must provide coverage for biomarker testing for the purposes of
33 diagnosis, treatment, appropriate management or ongoing monitoring of a disease or
34 condition of a subscriber or member when the test is supported by medical and scientific
35 evidence, including, but not limited to:

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

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

39 C. A warning or precaution on a label of a drug approved by the federal Food and
40 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 A contract described in this subsection must provide for coverage in a manner that limits
6 disruptions in care, including the need for multiple biopsies or biological specimen
7 samples.

8 **3. Utilization review.** If an individual and group nonprofit hospital and medical
9 services plan contract contains a provision whereby in nonemergency cases the insured is
10 required to be prospectively evaluated through a prehospital admission certification, a
11 preinpatient service eligibility program or any similar preutilization review or screening
12 procedure prior to biomarker testing, the utilization review entity or any 3rd party acting
13 on behalf of an organization or entity subject to this section must approve or deny a prior
14 authorization request and notify the subscriber or member, the subscriber's or member's
15 health care provider and any entity requesting authorization of the service within 72 hours
16 for nonurgent requests or within 24 hours for urgent requests.

17 **4. Application.** This section applies to a policy, contract and certificate, except those
18 designed to cover only specific diseases, accidental injury or dental procedures, executed,
19 delivered, issued for delivery, continued or renewed in this State. For purposes of this
20 section, a contract is deemed to be renewed no later than the next yearly anniversary of the
21 contract date.

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

23 **§2745-H. Biomarker testing insurance coverage**

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

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

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

36 C. "Consensus statement" means a statement:

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

40 (2) Aimed at specific clinical circumstances; and

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

1 D. "Nationally recognized clinical practice guideline" means an evidence-based
2 clinical practice guideline developed by an independent organization or medical
3 professional society using a transparent methodology and reporting structure and with
4 a conflict of interest policy that establishes a standard of care informed by a systematic
5 review of evidence and an assessment of the benefits and risks of alternative care
6 options and includes recommendations intended to optimize patient care.

7 **2. Required coverage.** An individual insurance policy, except those designed to cover
8 only specific diseases, accidental injury or dental procedures, must provide coverage for
9 biomarker testing for the purposes of diagnosis, treatment, appropriate management or
10 ongoing monitoring of a disease or condition of a person covered by the policy when the
11 test is supported by medical and scientific evidence, including, but not limited to:

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

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

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

17 D. A federal Department of Health and Human Services, Centers for Medicare and
18 Medicaid Services national coverage determination or Medicare administrative
19 contractor local coverage determination; or

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

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

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

32 **4. Application.** This section applies to a policy, contract and certificate executed,
33 delivered, issued for delivery, continued or renewed in this State. For purposes of this
34 section, a contract is deemed to be renewed no later than the next yearly anniversary of the
35 contract date.

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

37 **§2837-I. Biomarker testing insurance coverage**

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

40 A. "Biomarker" means a characteristic that is objectively measured and evaluated as
41 an indicator of a normal biological process, pathogenic process or pharmacologic
42 response to a specific therapeutic intervention, including a known gene-drug

1 interaction for a medication being considered for use or already being administered.
2 "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or
3 protein expression.

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

8 C. "Consensus statement" means a statement:

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

12 (2) Aimed at specific clinical circumstances; and

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

15 D. "Nationally recognized clinical practice guideline" means an evidence-based
16 clinical practice guideline developed by an independent organization or medical
17 professional society using a transparent methodology and reporting structure and with
18 a conflict of interest policy that establishes a standard of care informed by a systematic
19 review of evidence and an assessment of the benefits and risks of alternative care
20 options and includes recommendations intended to optimize patient care.

21 **2. Required coverage.** A group insurance policy, except those designed to cover only
22 specific diseases, accidental injury or dental procedures, must provide coverage for
23 biomarker testing for the purposes of diagnosis, treatment, appropriate management or
24 ongoing monitoring of a disease or condition of an insured person or subscriber covered by
25 that policy when the test is supported by medical and scientific evidence, including, but not
26 limited to:

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

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

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

32 D. A federal Department of Health and Human Services, Centers for Medicare and
33 Medicaid Services national coverage determination or Medicare administrative
34 contractor local coverage determination; or

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

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

39 **3. Utilization review.** If a group insurance policy contains a provision whereby in
40 nonemergency cases the insured is required to be prospectively evaluated through a
41 prehospital admission certification, a preinpatient service eligibility program or any similar
42 preutilization review or screening procedure prior to biomarker testing, the utilization

1 review entity or any 3rd party acting on behalf of an organization or entity subject to this
2 section must approve or deny a prior authorization request and notify the insured person or
3 subscriber covered by that policy, the insured person's or subscriber's health care provider
4 and any entity requesting authorization of the service within 72 hours for nonurgent
5 requests or within 24 hours for urgent requests.

6 **4. Application.** This section applies to a policy, contract and certificate executed,
7 delivered, issued for delivery, continued or renewed in this State. For purposes of this
8 section, a contract is deemed to be renewed no later than the next yearly anniversary of the
9 contract date.

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

11 **§4237-B. Biomarker testing insurance coverage**

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

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

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

24 C. "Consensus statement" means a statement:

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

28 (2) Aimed at specific clinical circumstances; and

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

31 D. "Nationally recognized clinical practice guideline" means an evidence-based
32 clinical practice guideline developed by an independent organization or medical
33 professional society using a transparent methodology and reporting structure and with
34 a conflict of interest policy that establishes a standard of care informed by a systematic
35 review of evidence and an assessment of the benefits and risks of alternative care
36 options and includes recommendations intended to optimize patient care.

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

