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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.

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.

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

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

§3174-KKK. Biomarker testing coverage

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

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

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

C. "Consensus statement" means a statement:

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

(2) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

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

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

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

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

§2320-H. Biomarker testing insurance coverage

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

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

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

C. "Consensus statement" means a statement:

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

(2) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

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

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

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

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

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

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

§2745-H. Biomarker testing insurance coverage

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

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

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

C. "Consensus statement" means a statement:

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

(2) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

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

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

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

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

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

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

§2837-I. Biomarker testing insurance coverage

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

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

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

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

C. "Consensus statement" means a statement:

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

(2) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

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

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

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

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

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

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

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

§4237-B. Biomarker testing insurance coverage

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

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

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

C. "Consensus statement" means a statement:

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

(2) Aimed at specific clinical circumstances; and

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

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

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

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

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

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

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

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

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

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

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

Sec. 6. Application. The requirements of the Maine Revised Statutes, Title 22, section 3174-KKK, Title 24, section 2320-H and Title 24-A, sections 2745-H, 2837-I and 4237-B apply to a policy, contract, certificate or other instrument of insurance coverage that takes effect or is renewed on or after the effective date of this Act.

SUMMARY

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