ASSEMBLY, No. 4163

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED APRIL 8, 2024

Sponsored by:
Assemblywoman SHAVONDA E. SUMTER
District 35 (Bergen and Passaic)
Assemblyman GARY S. SCHAER
District 36 (Bergen and Passaic)
Assemblywoman SHAMA A. HAIDER
District 37 (Bergen)

Co-Sponsored by:
Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin, Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn, Assemblymen Conaway, DePhillips, Calabrese, Barlas, Assemblywoman Speight, Assemblymen Spearman, DiMaio, Assemblywoman Peterpaul, Assemblymen McClellan, Simonsen, Hutchison, Verrelli, Assemblywoman Park and Assemblyman Stanley

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 9/23/2024)

AN ACT concerning health insurance coverage for biomarker testing and amending and supplementing various parts of the statutory law.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. a. Each hospital service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or FDA-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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

2. a. Each medical service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all medical service corporation contracts in which the medical service corporation has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

3. a. Each health service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all health service corporation contracts in which the health service corporation has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

4. a. Each individual health insurance policy that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to chapter 26 of Title 17B of the New Jersey Statutes or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an insured 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an insured.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the insured and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker testing for the insured shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

5. a. Each group health insurance policy that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to chapter 27 of Title 17B of the New Jersey Statutes or is approved for issuance or renewal in this State by

the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an insured 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an insured.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the insured and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker testing for the insured shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all policies in which the insurer has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

6. a. Each individual health benefits plan that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the

covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the health benefits plan.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

7. a. Each small employer health benefits plan that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the health benefits plan.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical

circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

8. a. Each health maintenance organization contract for health care services that is delivered, issued, executed, or renewed in this State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide health care services for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an enrollee 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an enrollee.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the enrollee and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The enrollee and the treating health care provider or treating health care entity prescribing biomarker testing for the enrollee shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The health care services shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to those contracts for health care services by health maintenance organizations under which the right to change the schedule of charges for enrollee coverage is reserved.

g. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

9. a. The State Health Benefits Commission shall ensure that every contract providing hospital or medical expense benefits, which is purchased by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), provides coverage for biomarker testing, as defined by subsection e. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing to the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

10. a. The School Employees' Health Benefits Commission shall ensure that every contract providing hospital or medical expense benefits, which is purchased by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), provides coverage for biomarker testing, as defined by subsection e. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means 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. The 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.

11. a. Notwithstanding any State law or regulation to the contrary, the Department of Human Services shall ensure that expenses incurred for biomarker testing shall be provided with no cost-sharing to persons served under the Medicaid program, established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an individual 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

d. If the Division of Medical Assistance and Health Services in the Department of Human Services contracts with a third-party entity to deliver biomarker testing services pursuant to this section to beneficiaries under the Medicaid program, the third-party entity shall provide biomarker testing at the same scope, duration and frequency as the Medicaid program otherwise provides to individuals.

e. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice be sent to an individual, the appropriate health care provider, and, if necessary, the requisite health care entity if the request for prior authorization was

submitted through the entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The individual and the treating health care provider or treating health care entity prescribing biomarker testing for the individual shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

f. As used in this section:

"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 shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

12. This act shall take effect on the 90th day next following enactment and shall apply to policies and contracts issued or renewed on or after the effective date.

STATEMENT

This bill requires health insurers to cover biomarker testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The evidence includes, but is 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 National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or (5) Nationally recognized clinical practice guidelines and consensus statements. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen

samples, in the care of an individual. The bill also stipulates timelines in which a decision on prior authorization is to be made.