[Second Reprint]

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)
Senator VIN GOPAL
District 11 (Monmouth)
Senator TROY SINGLETON
District 7 (Burlington)

Co-Sponsored by:
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SYNOPSIS

Requires health insurers to provide coverage for biomarker precision medical testing.

CURRENT VERSION OF TEXT

As amended by the Senate on March 24, 2025.

(Sponsorship Updated As Of: 3/24/2025)

AN ACT concerning health insurance coverage for biomarker [2]precision medical[2] testing [1]**[**and amending**]**[1] 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 [2]**[**P.L. , c. (C.) (pending before the Legislature as this bill)**]** this act[2], shall provide coverage for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a subscriber when the [2]**[**test is supported by medical and scientific evidence, including, but not limited to**]** efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a subscriber's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or FDA-cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]**[**and consensus statements**]**[2].

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) [1]**[**Notwithstanding any other law, rule, or regulation to the contrary, if**]** If[1] utilization review is required, [1]a hospital service corporation shall provide[1] a decision [1]**[**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

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Assembly AFI committee amendments adopted October 24, 2024.
[2]Senate floor amendments adopted March 24, 2025.

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] pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.][1]

"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 [2]⟦P.L. , c. (C.) (pending before the Legislature as this bill)⟧ this act[2], shall provide coverage for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a subscriber when the [2]⟦test is supported by medical and scientific evidence, including, but not limited to⟧ efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a subscriber's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]⟦and consensus statements⟧[2].

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) [1]⟦Notwithstanding any other law, rule, or regulation to the contrary, if⟧ If[1] utilization review is required, [1]a medical service corporation shall provide[1] a decision [1]⟦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⟧ pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et. al)[1].

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including

determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1][[]"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.[]][1]

"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 [2][[]P.L. , c. (C.) (pending before the Legislature as this bill)[]] this act[2], shall provide coverage for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding

asymptomatic screening, to guide treatment decisions[2] of a subscriber when the [2]⟦test is supported by medical and scientific evidence, including, but not limited to⟧ efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a subscriber's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]⟦and consensus statements⟧[2].

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) [1]⟦Notwithstanding any other law, rule, or regulation to the contrary, if⟧ If[1] utilization review is required, [1]a health service corporation shall provide[1] a decision [1]⟦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⟧ pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.][1]

"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 [2][P.L. , c. (C.) (pending before the Legislature as this bill)] this act[2], shall provide coverage for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of an insured when the [2][test is supported by medical and scientific evidence, including, but not limited to] efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for an insured's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2][and consensus statements]2.

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) [1][Notwithstanding any other law, rule, or regulation to the contrary, if] If1 utilization review is required, 1a carrier shall provide1 a decision [1][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] pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)1.

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker 2precision medical2 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 contract2, including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions2.

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 2precision medical2 testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker 2precision medical2 testing includes2,2 but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.**]**[1]

"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 [2]**[**P.L. , c. (C.) (pending before the Legislature as this bill)**]** this act[2], shall provide benefits for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of an insured when the [2]**[**test is supported by medical and scientific evidence, including, but not limited to**]** efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for an insured's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]**[**and consensus statements**]**[2].

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) [1]**[**Notwithstanding any other law, rule, or regulation to the contrary, if**]** If[1] utilization review is required, [1]an insurer shall provide[1] a decision [1]**[**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] pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.][1]

"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 [2][P.L. , c. (C.) (pending before the Legislature as this bill)] this act[2], shall provide benefits for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a covered person when the [2][test is supported by medical and scientific evidence, including, but not limited to] efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a covered person's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2][and consensus statements][2].

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) [1][Notwithstanding any other law, rule, or regulation to the contrary, if] If[1] utilization review is required, [1]a carrier shall provide[1] a decision [1][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] pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of

health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1][[]"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.[]][1]

"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 [2][]P.L. , c. (C.) (pending before the Legislature as this bill)[] this act[2], shall provide benefits for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a covered

person when the [2]⟦test is supported by medical and scientific evidence, including, but not limited to⟧ efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a covered person's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]⟦and consensus statements⟧[2].

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) [1]⟦Notwithstanding any other law, rule, or regulation to the contrary, if⟧ If[1] utilization review is required, [1]a carrier shall provide[1] a decision [1]⟦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⟧ pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.][1]

"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 [2][P.L. , c. (C.) (pending before the Legislature as this bill)] this act[2], shall provide health care services for biomarker [2]precision medical[2] testing, as defined by subsection g. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of an enrollee when the [2][test is supported by medical and scientific evidence, including, but not limited to] efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for an enrollee's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]⟦and consensus statements⟧[2].

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) [1]⟦Notwithstanding any other law, rule, or regulation to the contrary, if⟧ If[1] utilization review is required, [1]a health maintenance organization shall provide[1] a decision [1]⟦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⟧ pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The enrollee and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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[2], including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions[2].

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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]⟦"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.**]**[1]

"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 [2]**[**P.L. , c. (C.) (pending before the Legislature as this bill)**]** this act[2], provides coverage for biomarker [2]precision medical[2] testing, as defined by subsection e. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a covered person when the [2]**[**test is supported by medical and scientific evidence, including, but not limited to**]** efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a covered person's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]**[**and consensus statements**]**[2].

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) [1]**[**Notwithstanding any other law, rule, or regulation to the contrary, if**]** If[1] utilization review is required, a decision shall be rendered [1]**[**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**]** pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1][[]"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.[]][1]

"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 [2][[]P.L. , c. (C.) (pending before the Legislature as this bill)[]] this act[2], provides coverage for biomarker [2]precision medical[2] testing, as defined by subsection e. of this section.

b. Biomarker [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of a covered person when the [2][[]test is supported by medical and scientific evidence, including, but not limited to[]] efficacy and appropriateness

of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a covered person's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2][and consensus statements][2].

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) [1][Notwithstanding any other law, rule, or regulation to the contrary, if] If[1] utilization review is required, a decision shall be rendered [1][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] pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

[1]["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.**]**[1]

"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 [2]precision medical[2] 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 [2]precision medical[2] testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition[2], excluding asymptomatic screening, to guide treatment decisions[2] of an individual when the [2]**[**test is supported by medical and scientific evidence, including, but not limited to**]** efficacy and appropriateness of biomarker precision medical testing for the diagnosis, treatment, appropriate management, or guiding treatment decisions for an individual's disease or condition is recognized by[2]:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) [2]actions to address[2] 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 [2]**[**and consensus statements**]**[2].

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 [2]precision medical[2] testing services pursuant to this section to beneficiaries under the Medicaid program, the third-party entity shall provide biomarker [2]precision medical[2] testing at the same scope, duration and frequency as the Medicaid program otherwise provides to individuals.

e. (1) [1]⟦Notwithstanding any other law, rule, or regulation to the contrary, if⟧ If[1] utilization review is required, a decision [1]⟦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⟧ shall be provided pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)[1].

(2) The individual and the treating health care provider or treating health care entity prescribing biomarker [2]precision medical[2] 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 [2]precision medical[2] testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker [2]precision medical[2] testing includes[2],[2] 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.