

CHAPTER 49

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

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

C.17:48-6zz Biomarker precision medical testing coverage, hospital service corporation contracts.

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 this act, shall provide coverage for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or FDA-cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a hospital service corporation shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.17:48A-7ww Biomarker precision medical testing coverage, medical service corporation contracts.

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 this act, shall provide coverage for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a medical service corporation shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et. al).

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

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 precision medical testing” means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker precision medical testing includes,

but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

“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.

C.17:48E-35.50 Biomarker precision medical testing coverage, health service corporation contracts.

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 this act, shall provide coverage for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a health service corporation shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.17B:26-2.1ss Biomarker precision medical testing coverage, individual health insurance policies.

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 this act, shall provide coverage for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a carrier shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.17B:27-46.1yy Biomarker precision medical testing coverage, group health insurance policies.

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 this act, shall provide benefits for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, an insurer shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.17B:27A-7.34 Biomarker precision medical testing coverage, individual health benefits plans.

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 this act, shall provide benefits for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a carrier shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.17B:27A-19.38 Biomarker precision medical testing coverage, small employer health benefits plans.

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 this act, shall provide benefits for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a carrier shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

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

“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.

C.26:2J-4.51 Biomarker precision medical testing coverage, health maintenance organization contracts.

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 this act, shall provide health care services for biomarker precision medical testing, as defined by subsection g. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a health maintenance organization shall provide a decision pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

utilization review of health care services along with copayment, deductible, and coinsurance provisions.

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

“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.

C.52:14-17.29nn Biomarker precision medical testing coverage, State Health Benefits Commission contracts.

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 this act, provides coverage for biomarker precision medical testing, as defined by subsection e. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a decision shall be rendered pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

“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.

C.52:14-17.46.6w Biomarker precision medical testing coverage, School Employees’ Health Benefits Commission contracts.

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 this act, provides coverage for biomarker precision medical testing, as defined by subsection e. of this section.

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

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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) If utilization review is required, a decision shall be rendered pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

“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.

C.30:4D-6y Biomarker precision medical testing, Medicaid recipients, no cost-sharing.

11. a. Notwithstanding any State law or regulation to the contrary, the Department of Human Services shall ensure that expenses incurred for biomarker precision medical 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 precision medical testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition, excluding asymptomatic screening, to guide treatment decisions of an individual when the 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:

- (1) labeled indications for an FDA-approved or -cleared test;
- (2) indicated tests for an FDA-approved drug;
- (3) actions to address 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.

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

e. (1) If utilization review is required, a decision shall be provided pursuant to the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.).

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

Approved April 23, 2025.