

[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:

**Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin,
Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn,
Assemblymen DePhillips, Calabrese, Barlas, Assemblywoman Speight,
Assemblymen Spearman, DiMaio, Assemblywoman Peterpaul,
Assemblymen McClellan, Simonsen, Hutchison, Verrelli, Assemblywoman
Park, Assemblyman Stanley, Assemblywoman Reynolds-Jackson,
Assemblymen Azzariti Jr., Inganamort, Auth, Assemblywoman N.Munoz,
Assemblyman Schnall, Assemblywomen Drulis, Dunn, Morales, Ramirez,
Assemblyman Rodriguez, Assemblywoman Swain, Assemblyman Tully,
Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan,
McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer,
Wimberly and O'Scanlon**

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)

1 AN ACT concerning health insurance coverage for biomarker
 2 ²precision medical² testing ¹**and amending**¹ and supplementing
 3 various parts of the statutory law.

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

8 1. a. Each hospital service corporation contract that provides
 9 hospital or medical expense benefits and is delivered, issued,
 10 executed, or renewed in this State pursuant to P.L.1938, c.366
 11 (C.17:48-1 et seq.) or is approved for issuance or renewal in this
 12 State by the Commissioner of Banking and Insurance, on or after
 13 the effective date of ²**P.L. , c. (C.)** (pending before the
 14 Legislature as this bill) **this act**², shall provide coverage for
 15 biomarker ²precision medical² testing, as defined by subsection g. of
 16 this section.

17 b. Biomarker ²precision medical² testing shall be covered for
 18 the purposes of diagnosis, treatment, appropriate management, or
 19 ongoing monitoring of a disease or condition², excluding
 20 asymptomatic screening, to guide treatment decisions² of a subscriber
 21 when the ²**test is supported by medical and scientific evidence,**
 22 **including, but not limited to** efficacy and appropriateness of
 23 biomarker precision medical testing for the diagnosis, treatment,
 24 appropriate management, or guiding treatment decisions for a
 25 subscriber's disease or condition is recognized by²:

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

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

29 (3) ²actions to address² warnings and precautions on FDA-
 30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National
 32 Coverage Determinations or Medicare Administrative Contractor
 33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines ²**and**
 35 **consensus statements**².

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

39 d. (1) ¹**Notwithstanding any other law, rule, or regulation**
 40 **to the contrary, if** ¹**If** utilization review is required, ¹a hospital
 41 service corporation shall provide¹ a decision ¹**shall be rendered on**
 42 a prior authorization request, and notice shall be sent to the
 43 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:

¹Assembly AFI committee amendments adopted October 24, 2024.

²Senate floor amendments adopted March 24, 2025.

1 request is made through a health care entity, to the health care
2 entity, within 72 hours for a non-urgent request or 24 hours for an
3 urgent request] pursuant to the guidelines and timeframes set forth
4 in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

5 (2) The subscriber and the treating health care provider or
6 treating health care entity prescribing biomarker ²precision medical²
7 testing for the subscriber shall have access to clear, readily
8 accessible, and conspicuous information on the process to submit an
9 appeal to an adverse determination.

10 e. The benefits shall be provided to the same extent as for any
11 other medical condition under the contract², including
12 determinations of clinical review criteria used for utilization review of
13 health care services along with copayment, deductible, and
14 coinsurance provisions².

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

18 g. As used in this section:

19 “Biomarker” means a characteristic that is objectively measured
20 and evaluated as an indicator of normal biological processes,
21 pathogenic processes, or pharmacologic responses to a specific
22 therapeutic intervention, including known gene-drug interactions
23 for medications being considered for use or already being
24 administered. Biomarkers shall also include, but not be limited to,
25 gene mutations, characteristics of genes, or protein expression.

26 “Biomarker ²precision medical² testing” means the analysis of
27 tissue, blood, or other biospecimen for the presence of a biomarker.
28 Biomarker ²precision medical² testing includes^{2,2} but is not limited
29 to, single-analyte tests, multiplex panel tests, protein expression,
30 and whole exome, whole genome, and whole transcriptome
31 sequencing.

32 ¹“Consensus statement” means a statement developed by an
33 independent, multidisciplinary panel of experts utilizing a
34 transparent methodology and reporting structure and with a conflict
35 of interest policy. The statement shall be aimed at specific clinical
36 circumstances and be based on the best available evidence for the
37 purpose of optimizing the outcomes of clinical care.”¹

38 “Nationally-recognized clinical practice guidelines” means
39 evidence-based clinical practice guidelines developed by
40 independent organizations or medical professional societies
41 utilizing a transparent methodology and reporting structure and with
42 a conflict of interest policy. The guidelines establish standards of
43 care informed by a systematic review of evidence and an
44 assessment of the benefits and risks of alternative care options and
45 include recommendations intended to optimize patient care.

1 2. a. Each medical service corporation contract that provides
2 hospital or medical expense benefits and is delivered, issued,
3 executed, or renewed in this State pursuant to P.L.1940, c.74
4 (C.17:48A-1 et seq.) or is approved for issuance or renewal in this
5 State by the Commissioner of Banking and Insurance, on or after
6 the effective date of ²[P.L. , c. (C.) (pending before the
7 Legislature as this bill)] this act², shall provide coverage for
8 biomarker ²precision medical² testing, as defined by subsection g. of
9 this section.

10 b. Biomarker ²precision medical² testing shall be covered for
11 the purposes of diagnosis, treatment, appropriate management, or
12 ongoing monitoring of a disease or condition², excluding
13 asymptomatic screening, to guide treatment decisions² of a subscriber
14 when the ²[test is supported by medical and scientific evidence,
15 including, but not limited to] efficacy and appropriateness of
16 biomarker precision medical testing for the diagnosis, treatment,
17 appropriate management, or guiding treatment decisions for a
18 subscriber's disease or condition is recognized by²:

- 19 (1) labeled indications for an FDA-approved or -cleared test;
20 (2) indicated tests for an FDA-approved drug;
21 (3) ²actions to address² warnings and precautions on FDA-
22 approved drug labels;
23 (4) Centers for Medicare and Medicaid Services National
24 Coverage Determinations or Medicare Administrative Contractor
25 Local Coverage Determinations; or
26 (5) nationally-recognized clinical practice guidelines ²[and
27 consensus statements]².

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

31 d. (1) ¹[Notwithstanding any other law, rule, or regulation
32 to the contrary, if] If¹ utilization review is required, ¹a medical
33 service corporation shall provide¹ a decision ¹[shall be rendered on
34 a prior authorization request, and notice shall be sent to the
35 subscriber and the appropriate health care provider, and if the
36 request is made through a health care entity, to the health care
37 entity, within 72 hours for a non-urgent request or 24 hours for an
38 urgent request] pursuant to the guidelines and timeframes set forth
39 in P.L.2023, c.296 (C.17B:30-55.1 et. al)¹.

40 (2) The subscriber and the treating health care provider or
41 treating health care entity prescribing biomarker ²precision medical²
42 testing for the subscriber shall have access to clear, readily
43 accessible, and conspicuous information on the process to submit an
44 appeal to an adverse determination.

45 e. The benefits shall be provided to the same extent as for any
46 other medical condition under the contract², including

1 determinations of clinical review criteria used for utilization review of
2 health care services along with copayment, deductible, and
3 coinsurance provisions².

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

7 g. As used in this section:

8 “Biomarker” means a characteristic that is objectively measured
9 and evaluated as an indicator of normal biological processes,
10 pathogenic processes, or pharmacologic responses to a specific
11 therapeutic intervention, including known gene-drug interactions
12 for medications being considered for use or already being
13 administered. Biomarkers shall also include, but not be limited to,
14 gene mutations, characteristics of genes, or protein expression.

15 “Biomarker ²precision medical² testing” means the analysis of
16 tissue, blood, or other biospecimen for the presence of a biomarker.
17 Biomarker ²precision medical² testing includes^{2,2} but is not limited
18 to, single-analyte tests, multiplex panel tests, protein expression,
19 and whole exome, whole genome, and whole transcriptome
20 sequencing.

21 ¹【“Consensus statement” means a statement developed by an
22 independent, multidisciplinary panel of experts utilizing a
23 transparent methodology and reporting structure and with a conflict
24 of interest policy. The statement shall be aimed at specific clinical
25 circumstances and be based on the best available evidence for the
26 purpose of optimizing the outcomes of clinical care.】¹

27 “Nationally-recognized clinical practice guidelines” means
28 evidence-based clinical practice guidelines developed by
29 independent organizations or medical professional societies
30 utilizing a transparent methodology and reporting structure and with
31 a conflict of interest policy. The guidelines establish standards of
32 care informed by a systematic review of evidence and an
33 assessment of the benefits and risks of alternative care options and
34 include recommendations intended to optimize patient care.

35
36 3. a. Each health service corporation contract that provides
37 hospital or medical expense benefits and is delivered, issued,
38 executed, or renewed in this State pursuant to P.L.1985, c.236
39 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this
40 State by the Commissioner of Banking and Insurance, on or after
41 the effective date of ²【P.L. , c. (C.) (pending before the
42 Legislature as this bill)】 this act², shall provide coverage for
43 biomarker ²precision medical² testing, as defined by subsection g. of
44 this section.

45 b. Biomarker ²precision medical² testing shall be covered for
46 the purposes of diagnosis, treatment, appropriate management, or
47 ongoing monitoring of a disease or condition², excluding

1 asymptomatic screening, to guide treatment decisions² of a subscriber
2 when the ²**test is supported by medical and scientific evidence,**
3 **including, but not limited to** efficacy and appropriateness of
4 biomarker precision medical testing for the diagnosis, treatment,
5 appropriate management, or guiding treatment decisions for a
6 subscriber's disease or condition is recognized by²:

- 7 (1) labeled indications for an FDA-approved or -cleared test;
8 (2) indicated tests for an FDA-approved drug;
9 (3) ²actions to address² warnings and precautions on FDA-
10 approved drug labels;
11 (4) Centers for Medicare and Medicaid Services National
12 Coverage Determinations or Medicare Administrative Contractor
13 Local Coverage Determinations; or
14 (5) nationally-recognized clinical practice guidelines ²**and**
15 **consensus statements**².

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

19 d. (1) ¹**Notwithstanding any other law, rule, or regulation**
20 **to the contrary, if** If¹ utilization review is required, ¹a health
21 service corporation shall provide¹ a decision ¹**shall be rendered on**
22 **a prior authorization request, and notice shall be sent to the**
23 **subscriber and the appropriate health care provider, and if the**
24 **request is made through a health care entity, to the health care**
25 **entity, within 72 hours for a non-urgent request or 24 hours for an**
26 **urgent request** pursuant to the guidelines and timeframes set forth
27 in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

28 (2) The subscriber and the treating health care provider or
29 treating health care entity prescribing biomarker ²precision medical²
30 testing for the subscriber shall have access to clear, readily
31 accessible, and conspicuous information on the process to submit an
32 appeal to an adverse determination.

33 e. The benefits shall be provided to the same extent as for any
34 other medical condition under the contract², including
35 determinations of clinical review criteria used for utilization review of
36 health care services along with copayment, deductible, and
37 coinsurance provisions².

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

41 g. As used in this section:

42 "Biomarker" means a characteristic that is objectively measured
43 and evaluated as an indicator of normal biological processes,
44 pathogenic processes, or pharmacologic responses to a specific
45 therapeutic intervention, including known gene-drug interactions
46 for medications being considered for use or already being

1 administered. Biomarkers shall also include, but not be limited to,
2 gene mutations, characteristics of genes, or protein expression.

3 “Biomarker ²precision medical² testing” means the analysis of
4 tissue, blood, or other biospecimen for the presence of a biomarker.
5 Biomarker ²precision medical² testing includes^{2, 2} but is not limited
6 to, single-analyte tests, multiplex panel tests, protein expression,
7 and whole exome, whole genome, and whole transcriptome
8 sequencing.

9 ¹“Consensus statement” means a statement developed by an
10 independent, multidisciplinary panel of experts utilizing a
11 transparent methodology and reporting structure and with a conflict
12 of interest policy. The statement shall be aimed at specific clinical
13 circumstances and be based on the best available evidence for the
14 purpose of optimizing the outcomes of clinical care.¹

15 “Nationally-recognized clinical practice guidelines” means
16 evidence-based clinical practice guidelines developed by
17 independent organizations or medical professional societies
18 utilizing a transparent methodology and reporting structure and with
19 a conflict of interest policy. The guidelines establish standards of
20 care informed by a systematic review of evidence and an
21 assessment of the benefits and risks of alternative care options and
22 include recommendations intended to optimize patient care.

23

24 4. a. Each individual health insurance policy that provides
25 hospital or medical expense benefits and is delivered, issued,
26 executed, or renewed in this State pursuant to chapter 26 of Title
27 17B of the New Jersey Statutes or is approved for issuance or
28 renewal in this State by the Commissioner of Banking and
29 Insurance, on or after the effective date of ²【P.L. , c. (C.)
30 (pending before the Legislature as this bill)】 this act², shall provide
31 coverage for biomarker ²precision medical² testing, as defined by
32 subsection g. of this section.

33 b. Biomarker ²precision medical² testing shall be covered for
34 the purposes of diagnosis, treatment, appropriate management, or
35 ongoing monitoring of a disease or condition², excluding
36 asymptomatic screening, to guide treatment decisions² of an insured
37 when the ²【test is supported by medical and scientific evidence,
38 including, but not limited to】 efficacy and appropriateness of
39 biomarker precision medical testing for the diagnosis, treatment,
40 appropriate management, or guiding treatment decisions for an
41 insured’s disease or condition is recognized by²:

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

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

44 (3) actions to address² warnings and precautions on FDA-
45 approved drug labels;

1 (4) Centers for Medicare and Medicaid Services National
2 Coverage Determinations or Medicare Administrative Contractor
3 Local Coverage Determinations; or

4 (5) nationally-recognized clinical practice guidelines ²and
5 consensus statements².

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

9 d. (1) ¹Notwithstanding any other law, rule, or regulation
10 to the contrary, if ¹If utilization review is required, ¹a carrier shall
11 provide¹ a decision ¹shall be rendered on a prior authorization
12 request, and notice shall be sent to the insured and the appropriate
13 health care provider, and if the request is made through a health
14 care entity, to the health care entity, within 72 hours for a non-
15 urgent request or 24 hours for an urgent request ¹pursuant to the
16 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-
17 55.1 et al.)¹.

18 (2) The insured and the treating health care provider or treating
19 health care entity prescribing biomarker ²precision medical² testing
20 for the insured shall have access to clear, readily accessible, and
21 conspicuous information on the process to submit an appeal to an
22 adverse determination.

23 e. The benefits shall be provided to the same extent as for any
24 other medical condition under the contract², including
25 determinations of clinical review criteria used for utilization review of
26 health care services along with copayment, deductible, and
27 coinsurance provisions².

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

31 g. As used in this section:

32 “Biomarker” means a characteristic that is objectively measured
33 and evaluated as an indicator of normal biological processes,
34 pathogenic processes, or pharmacologic responses to a specific
35 therapeutic intervention, including known gene-drug interactions
36 for medications being considered for use or already being
37 administered. Biomarkers shall also include, but not be limited to,
38 gene mutations, characteristics of genes, or protein expression.

39 “Biomarker ²precision medical² testing” means the analysis of
40 tissue, blood, or other biospecimen for the presence of a biomarker.
41 Biomarker ²precision medical² testing includes^{2,2} but is not limited
42 to, single-analyte tests, multiplex panel tests, protein expression,
43 and whole exome, whole genome, and whole transcriptome
44 sequencing.

45 ¹“Consensus statement” means a statement developed by an
46 independent, multidisciplinary panel of experts utilizing a
47 transparent methodology and reporting structure and with a conflict

1 of interest policy. The statement shall be aimed at specific clinical
2 circumstances and be based on the best available evidence for the
3 purpose of optimizing the outcomes of clinical care.】¹

4 “Nationally-recognized clinical practice guidelines” means
5 evidence-based clinical practice guidelines developed by
6 independent organizations or medical professional societies
7 utilizing a transparent methodology and reporting structure and with
8 a conflict of interest policy. The guidelines establish standards of
9 care informed by a systematic review of evidence and an
10 assessment of the benefits and risks of alternative care options and
11 include recommendations intended to optimize patient care.

12
13 5. a. Each group health insurance policy that provides hospital
14 or medical expense benefits and is delivered, issued, executed, or
15 renewed in this State pursuant to chapter 27 of Title 17B of the New
16 Jersey Statutes or is approved for issuance or renewal in this State
17 by the Commissioner of Banking and Insurance, on or after the
18 effective date of ²【P.L. , c. (C.) (pending before the
19 Legislature as this bill)】 this act², shall provide benefits for
20 biomarker ²precision medical² testing, as defined by subsection g. of
21 this section.

22 b. Biomarker ²precision medical² testing shall be covered for
23 the purposes of diagnosis, treatment, appropriate management, or
24 ongoing monitoring of a disease or condition², excluding
25 asymptomatic screening, to guide treatment decisions² of an insured
26 when the ²【test is supported by medical and scientific evidence,
27 including, but not limited to】 efficacy and appropriateness of
28 biomarker precision medical testing for the diagnosis, treatment,
29 appropriate management, or guiding treatment decisions for an
30 insured’s disease or condition is recognized by²:

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

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

33 (3) ²actions to address² warnings and precautions on FDA-
34 approved drug labels;

35 (4) Centers for Medicare and Medicaid Services National
36 Coverage Determinations or Medicare Administrative Contractor
37 Local Coverage Determinations; or

38 (5) nationally-recognized clinical practice guidelines ²【and
39 consensus statements】².

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

43 d. (1) ¹【Notwithstanding any other law, rule, or regulation
44 to the contrary, if】 If¹ utilization review is required, ¹an insurer
45 shall provide¹ a decision ¹【shall be rendered on a prior
46 authorization request, and notice shall be sent to the insured and the

1 appropriate health care provider, and if the request is made through
2 a health care entity, to the health care entity, within 72 hours for a
3 non-urgent request or 24 hours for an urgent request **】 pursuant to**
4 the guidelines and timeframes set forth in P.L.2023, c.296
5 (C.17B:30-55.1 et al.)¹.

6 (2) The insured and the treating health care provider or treating
7 health care entity prescribing biomarker ²precision medical² testing
8 for the insured shall have access to clear, readily accessible, and
9 conspicuous information on the process to submit an appeal to an
10 adverse determination.

11 e. The benefits shall be provided to the same extent as for any
12 other medical condition under the contract², including
13 determinations of clinical review criteria used for utilization review of
14 health care services along with copayment, deductible, and
15 coinsurance provisions².

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

18 g. As used in this section:

19 “Biomarker” means a characteristic that is objectively measured
20 and evaluated as an indicator of normal biological processes,
21 pathogenic processes, or pharmacologic responses to a specific
22 therapeutic intervention, including known gene-drug interactions
23 for medications being considered for use or already being
24 administered. Biomarkers shall also include, but not be limited to,
25 gene mutations, characteristics of genes, or protein expression.

26 “Biomarker ²precision medical² testing” means the analysis of
27 tissue, blood, or other biospecimen for the presence of a biomarker.
28 Biomarker ²precision medical² testing includes^{2,2} but is not limited
29 to, single-analyte tests, multiplex panel tests, protein expression,
30 and whole exome, whole genome, and whole transcriptome
31 sequencing.

32 ¹**【**“Consensus statement” means a statement developed by an
33 independent, multidisciplinary panel of experts utilizing a
34 transparent methodology and reporting structure and with a conflict
35 of interest policy. The statement shall be aimed at specific clinical
36 circumstances and be based on the best available evidence for the
37 purpose of optimizing the outcomes of clinical care.**】¹**

38 “Nationally-recognized clinical practice guidelines” means
39 evidence-based clinical practice guidelines developed by
40 independent organizations or medical professional societies
41 utilizing a transparent methodology and reporting structure and with
42 a conflict of interest policy. The guidelines establish standards of
43 care informed by a systematic review of evidence and an
44 assessment of the benefits and risks of alternative care options and
45 include recommendations intended to optimize patient care.

1 6. a. Each individual health benefits plan that provides hospital
 2 or medical expense benefits and is delivered, issued, executed, or
 3 renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et
 4 seq.) or is approved for issuance or renewal in this State by the
 5 Commissioner of Banking and Insurance, on or after the effective
 6 date of ²[P.L. , c. (C.) (pending before the Legislature as
 7 this bill)] this act², shall provide benefits for biomarker ²precision
 8 medical² testing, as defined by subsection g. of this section.

9 b. Biomarker ²precision medical² testing shall be covered for
 10 the purposes of diagnosis, treatment, appropriate management, or
 11 ongoing monitoring of a disease or condition², excluding
 12 asymptomatic screening, to guide treatment decisions² of a covered
 13 person when the ²[test is supported by medical and scientific
 14 evidence, including, but not limited to] efficacy and appropriateness
 15 of biomarker precision medical testing for the diagnosis, treatment,
 16 appropriate management, or guiding treatment decisions for a covered
 17 person's disease or condition is recognized by²:

- 18 (1) labeled indications for an FDA-approved or -cleared test;
- 19 (2) indicated tests for an FDA-approved drug;
- 20 (3) ²actions to address² warnings and precautions on FDA-
 21 approved drug labels;
- 22 (4) Centers for Medicare and Medicaid Services National
 23 Coverage Determinations or Medicare Administrative Contractor
 24 Local Coverage Determinations; or
- 25 (5) nationally-recognized clinical practice guidelines ²[and
 26 consensus statements]².

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

30 d. (1) ¹[Notwithstanding any other law, rule, or regulation
 31 to the contrary, if] If¹ utilization review is required, ¹a carrier shall
 32 provide¹ a decision ¹[shall be rendered on a prior authorization
 33 request, and notice shall be sent to the covered person and the
 34 appropriate health care provider, and if the request is made through
 35 a health care entity, to the health care entity, within 72 hours for a
 36 non-urgent request or 24 hours for an urgent request] pursuant to
 37 the guidelines and timeframes set forth in P.L.2023, c.296
 38 (C.17B:30-55.1 et al.)¹.

39 (2) The covered person and the treating health care provider or
 40 treating health care entity prescribing biomarker ²precision medical²
 41 testing for the covered person shall have access to clear, readily
 42 accessible, and conspicuous information on the process to submit an
 43 appeal to an adverse determination.

44 e. The benefits shall be provided to the same extent as for any
 45 other medical condition under the health benefits plan², including
 46 determinations of clinical review criteria used for utilization review of

1 health care services along with copayment, deductible, and
2 coinsurance provisions².

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

6 g. As used in this section:

7 “Biomarker” means a characteristic that is objectively measured
8 and evaluated as an indicator of normal biological processes,
9 pathogenic processes, or pharmacologic responses to a specific
10 therapeutic intervention, including known gene-drug interactions
11 for medications being considered for use or already being
12 administered. Biomarkers shall also include, but not be limited to,
13 gene mutations, characteristics of genes, or protein expression.

14 “Biomarker ²precision medical² testing” means the analysis of
15 tissue, blood, or other biospecimen for the presence of a biomarker.
16 Biomarker ²precision medical² testing includes^{2,2} but is not limited
17 to, single-analyte tests, multiplex panel tests, protein expression,
18 and whole exome, whole genome, and whole transcriptome
19 sequencing.

20 ¹“Consensus statement” means a statement developed by an
21 independent, multidisciplinary panel of experts utilizing a
22 transparent methodology and reporting structure and with a conflict
23 of interest policy. The statement shall be aimed at specific clinical
24 circumstances and be based on the best available evidence for the
25 purpose of optimizing the outcomes of clinical care.”¹

26 “Nationally-recognized clinical practice guidelines” means
27 evidence-based clinical practice guidelines developed by
28 independent organizations or medical professional societies
29 utilizing a transparent methodology and reporting structure and with
30 a conflict of interest policy. The guidelines establish standards of
31 care informed by a systematic review of evidence and an
32 assessment of the benefits and risks of alternative care options and
33 include recommendations intended to optimize patient care.

34

35 7. a. Each small employer health benefits plan that provides
36 hospital or medical expense benefits and is delivered, issued,
37 executed, or renewed in this State pursuant to P.L.1992, c.162
38 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in
39 this State by the Commissioner of Banking and Insurance, on or
40 after the effective date of ²“P.L. , c. (C.) (pending before
41 the Legislature as this bill)” this act², shall provide benefits for
42 biomarker ²precision medical² testing, as defined by subsection g. of
43 this section.

44 b. Biomarker ²precision medical² testing shall be covered for
45 the purposes of diagnosis, treatment, appropriate management, or
46 ongoing monitoring of a disease or condition², excluding
47 asymptomatic screening, to guide treatment decisions² of a covered

1 person when the ²test is supported by medical and scientific
2 evidence, including, but not limited to ¹ efficacy and appropriateness
3 of biomarker precision medical testing for the diagnosis, treatment,
4 appropriate management, or guiding treatment decisions for a covered
5 person's disease or condition is recognized by²:

- 6 (1) labeled indications for an FDA-approved or -cleared test;
7 (2) indicated tests for an FDA-approved drug;
8 (3) ²actions to address² warnings and precautions on FDA-
9 approved drug labels;
10 (4) Centers for Medicare and Medicaid Services National
11 Coverage Determinations or Medicare Administrative Contractor
12 Local Coverage Determinations; or
13 (5) nationally-recognized clinical practice guidelines ²and
14 consensus statements².

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

18 d. (1) ¹Notwithstanding any other law, rule, or regulation
19 to the contrary, if ¹ If utilization review is required, ¹a carrier shall
20 provide¹ a decision ¹shall be rendered on a prior authorization
21 request, and notice shall be sent to the covered person and the
22 appropriate health care provider, and if the request is made through
23 a health care entity, to the health care entity, within 72 hours for a
24 non-urgent request or 24 hours for an urgent request ¹ pursuant to
25 the guidelines and timeframes set forth in P.L.2023, c.296
26 (C.17B:30-55.1 et al.)¹.

27 (2) The covered person and the treating health care provider or
28 treating health care entity prescribing biomarker ²precision medical²
29 testing for the covered person shall have access to clear, readily
30 accessible, and conspicuous information on the process to submit an
31 appeal to an adverse determination.

32 e. The benefits shall be provided to the same extent as for any
33 other medical condition under the health benefits plan², including
34 determinations of clinical review criteria used for utilization review of
35 health care services along with copayment, deductible, and
36 coinsurance provisions².

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

40 g. As used in this section:

41 "Biomarker" means a characteristic that is objectively measured
42 and evaluated as an indicator of normal biological processes,
43 pathogenic processes, or pharmacologic responses to a specific
44 therapeutic intervention, including known gene-drug interactions
45 for medications being considered for use or already being
46 administered. Biomarkers shall also include, but not be limited to,
47 gene mutations, characteristics of genes, or protein expression.

1 “Biomarker ²precision medical² testing” means the analysis of
2 tissue, blood, or other biospecimen for the presence of a biomarker.
3 Biomarker ²precision medical² testing includes^{2,2} but is not limited
4 to, single-analyte tests, multiplex panel tests, protein expression,
5 and whole exome, whole genome, and whole transcriptome
6 sequencing.

7 ¹“Consensus statement” means a statement developed by an
8 independent, multidisciplinary panel of experts utilizing a
9 transparent methodology and reporting structure and with a conflict
10 of interest policy. The statement shall be aimed at specific clinical
11 circumstances and be based on the best available evidence for the
12 purpose of optimizing the outcomes of clinical care.¹

13 “Nationally-recognized clinical practice guidelines” means
14 evidence-based clinical practice guidelines developed by
15 independent organizations or medical professional societies
16 utilizing a transparent methodology and reporting structure and with
17 a conflict of interest policy. The guidelines establish standards of
18 care informed by a systematic review of evidence and an
19 assessment of the benefits and risks of alternative care options and
20 include recommendations intended to optimize patient care.

21
22 8. a. Each health maintenance organization contract for health
23 care services that is delivered, issued, executed, or renewed in this
24 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved
25 for issuance or renewal in this State by the Commissioner of
26 Banking and Insurance, on or after the effective date of
27 ²[P.L. , c. (C.) (pending before the Legislature as this
28 bill)] this act², shall provide health care services for biomarker
29 ²precision medical² testing, as defined by subsection g. of this
30 section.

31 b. Biomarker ²precision medical² testing shall be covered for
32 the purposes of diagnosis, treatment, appropriate management, or
33 ongoing monitoring of a disease or condition², excluding
34 asymptomatic screening, to guide treatment decisions² of an enrollee
35 when the ²[test is supported by medical and scientific evidence,
36 including, but not limited to] efficacy and appropriateness of
37 biomarker precision medical testing for the diagnosis, treatment,
38 appropriate management, or guiding treatment decisions for an
39 enrollee’s disease or condition is recognized by²:

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

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

42 (3) ²actions to address² warnings and precautions on FDA-
43 approved drug labels;

44 (4) Centers for Medicare and Medicaid Services National
45 Coverage Determinations or Medicare Administrative Contractor
46 Local Coverage Determinations; or

1 (5) nationally-recognized clinical practice guidelines ²and
2 consensus statements².

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

6 d. (1) ¹Notwithstanding any other law, rule, or regulation
7 to the contrary, if ¹If ¹utilization review is required, ¹a health
8 maintenance organization shall provide¹ a decision ¹shall be
9 rendered on a prior authorization request, and notice shall be sent to
10 the enrollee and the appropriate health care provider, and if the
11 request is made through a health care entity, to the health care
12 entity, within 72 hours for a non-urgent request or 24 hours for an
13 urgent request ¹pursuant to the guidelines and timeframes set forth
14 in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

15 (2) The enrollee and the treating health care provider or treating
16 health care entity prescribing biomarker ²precision medical² testing
17 for the enrollee shall have access to clear, readily accessible, and
18 conspicuous information on the process to submit an appeal to an
19 adverse determination.

20 e. The health care services shall be provided to the same extent
21 as for any other medical condition under the contract², including
22 determinations of clinical review criteria used for utilization review of
23 health care services along with copayment, deductible, and
24 coinsurance provisions².

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

29 g. As used in this section:

30 “Biomarker” means a characteristic that is objectively measured
31 and evaluated as an indicator of normal biological processes,
32 pathogenic processes, or pharmacologic responses to a specific
33 therapeutic intervention, including known gene-drug interactions
34 for medications being considered for use or already being
35 administered. Biomarkers shall also include, but not be limited to,
36 gene mutations, characteristics of genes, or protein expression.

37 “Biomarker ²precision medical² testing” means the analysis of
38 tissue, blood, or other biospecimen for the presence of a biomarker.
39 Biomarker ²precision medical² testing includes^{2,2} but is not limited
40 to, single-analyte tests, multiplex panel tests, protein expression,
41 and whole exome, whole genome, and whole transcriptome
42 sequencing.

43 ¹“Consensus statement” means a statement developed by an
44 independent, multidisciplinary panel of experts utilizing a
45 transparent methodology and reporting structure and with a conflict
46 of interest policy. The statement shall be aimed at specific clinical

1 circumstances and be based on the best available evidence for the
2 purpose of optimizing the outcomes of clinical care.¹

3 “Nationally-recognized clinical practice guidelines” means
4 evidence-based clinical practice guidelines developed by
5 independent organizations or medical professional societies
6 utilizing a transparent methodology and reporting structure and with
7 a conflict of interest policy. The guidelines establish standards of
8 care informed by a systematic review of evidence and an
9 assessment of the benefits and risks of alternative care options and
10 include recommendations intended to optimize patient care.

11
12 9. a. The State Health Benefits Commission shall ensure that
13 every contract providing hospital or medical expense benefits,
14 which is purchased by the commission on or after the effective date
15 of ²[P.L. , c. (C.) (pending before the Legislature as this
16 bill)] this act², provides coverage for biomarker ²precision medical²
17 testing, as defined by subsection e. of this section.

18 b. Biomarker ²precision medical² testing shall be covered for
19 the purposes of diagnosis, treatment, appropriate management, or
20 ongoing monitoring of a disease or condition², excluding
21 asymptomatic screening, to guide treatment decisions² of a covered
22 person when the ²[test is supported by medical and scientific
23 evidence, including, but not limited to] efficacy and appropriateness
24 of biomarker precision medical testing for the diagnosis, treatment,
25 appropriate management, or guiding treatment decisions for a covered
26 person’s disease or condition is recognized by²:

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

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

29 (3) ²actions to address² warnings and precautions on FDA-
30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National
32 Coverage Determinations or Medicare Administrative Contractor
33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines ²[and
35 consensus statements]².

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

39 d. (1) ¹[Notwithstanding any other law, rule, or regulation
40 to the contrary, if] If¹ utilization review is required, a decision shall
41 be rendered ¹[on a prior authorization request, and notice shall be
42 sent to the covered person and the appropriate health care provider,
43 and if the request is made through a health care entity, to the health
44 care entity, within 72 hours for a non-urgent request or 24 hours for
45 an urgent request] pursuant to the guidelines and timeframes set
46 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 ²precision medical² 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 ²precision medical² testing” means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker ²precision medical² 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 act², provides coverage for biomarker ²precision medical² testing, as defined by subsection e. of this section.

b. Biomarker ²precision medical² testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition², excluding asymptomatic screening, to guide treatment decisions² of a covered person when the ²[test is supported by medical and scientific evidence, including, but not limited to] efficacy and appropriateness

1 of biomarker precision medical testing for the diagnosis, treatment,
2 appropriate management, or guiding treatment decisions for a covered
3 person's disease or condition is recognized by²:

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

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

6 (3) ²actions to address² warnings and precautions on FDA-
7 approved drug labels;

8 (4) Centers for Medicare and Medicaid Services National
9 Coverage Determinations or Medicare Administrative Contractor
10 Local Coverage Determinations; or

11 (5) nationally-recognized clinical practice guidelines ²and
12 consensus statements².

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

16 d. (1) ¹Notwithstanding any other law, rule, or regulation
17 to the contrary, if ¹If utilization review is required, a decision shall
18 be rendered ¹on a prior authorization request, and notice shall be
19 sent to the covered person and the appropriate health care provider,
20 and if the request is made through a health care entity, to the health
21 care entity, within 72 hours for a non-urgent request or 24 hours for
22 an urgent request ¹pursuant to the guidelines and timeframes set
23 forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

24 (2) The covered person and the treating health care provider or
25 treating health care entity prescribing biomarker ²precision medical²
26 testing for the covered person shall have access to clear, readily
27 accessible, and conspicuous information on the process to submit an
28 appeal to an adverse determination.

29 e. As used in this section:

30 “Biomarker” means a characteristic that is objectively measured
31 and evaluated as an indicator of normal biological processes,
32 pathogenic processes, or pharmacologic responses to a specific
33 therapeutic intervention, including known gene-drug interactions
34 for medications being considered for use or already being
35 administered. Biomarkers shall also include, but not be limited to,
36 gene mutations, characteristics of genes, or protein expression.

37 “Biomarker ²precision medical² testing” means the analysis of
38 tissue, blood, or other biospecimen for the presence of a biomarker.
39 Biomarker ²precision medical² testing includes^{2,2} but is not limited
40 to, single-analyte tests, multiplex panel tests, protein expression,
41 and whole exome, whole genome, and whole transcriptome
42 sequencing.

43 ¹“Consensus statement” means a statement developed by an
44 independent, multidisciplinary panel of experts utilizing a
45 transparent methodology and reporting structure and with a conflict
46 of interest policy. The statement shall be aimed at specific clinical

1 circumstances and be based on the best available evidence for the
2 purpose of optimizing the outcomes of clinical care.】¹

3 “Nationally-recognized clinical practice guidelines” means
4 evidence-based clinical practice guidelines developed by
5 independent organizations or medical professional societies
6 utilizing a transparent methodology and reporting structure and with
7 a conflict of interest policy. The guidelines establish standards of
8 care informed by a systematic review of evidence and an
9 assessment of the benefits and risks of alternative care options and
10 include recommendations intended to optimize patient care.

11
12 11. a. Notwithstanding any State law or regulation to the
13 contrary, the Department of Human Services shall ensure that
14 expenses incurred for biomarker ²precision medical² testing shall be
15 provided with no cost-sharing to persons served under the Medicaid
16 program, established pursuant to P.L.1968, c.413 (C.30:4D-
17 1 et seq.).

18 b. Biomarker ²precision medical² testing shall be covered for
19 the purposes of diagnosis, treatment, appropriate management, or
20 ongoing monitoring of a disease or condition², excluding
21 asymptomatic screening, to guide treatment decisions² of an
22 individual when the ²【test is supported by medical and scientific
23 evidence, including, but not limited to】 efficacy and appropriateness
24 of biomarker precision medical testing for the diagnosis, treatment,
25 appropriate management, or guiding treatment decisions for an
26 individual’s disease or condition is recognized by²:

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

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

29 (3) ²actions to address² warnings and precautions on FDA-
30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National
32 Coverage Determinations or Medicare Administrative Contractor
33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines ²【and
35 consensus statements】².

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

39 d. If the Division of Medical Assistance and Health Services in
40 the Department of Human Services contracts with a third-party
41 entity to deliver biomarker ²precision medical² testing services
42 pursuant to this section to beneficiaries under the Medicaid
43 program, the third-party entity shall provide biomarker ²precision
44 medical² testing at the same scope, duration and frequency as the
45 Medicaid program otherwise provides to individuals.

1 e. (1) ¹【Notwithstanding any other law, rule, or regulation
2 to the contrary, if】 If¹ utilization review is required, a decision
3 ¹【shall be rendered on a prior authorization request, and notice be
4 sent to an individual, the appropriate health care provider, and, if
5 necessary, the requisite health care entity if the request for prior
6 authorization was submitted through the entity, within 72 hours for
7 a non-urgent request or 24 hours for an urgent request】 shall be
8 provided pursuant to the guidelines and timeframes set forth in
9 P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

10 (2) The individual and the treating health care provider or
11 treating health care entity prescribing biomarker ²precision medical²
12 testing for the individual shall have access to clear, readily
13 accessible, and conspicuous information on the process to submit an
14 appeal to an adverse determination.

15 f. As used in this section:

16 “Biomarker” means a characteristic that is objectively measured
17 and evaluated as an indicator of normal biological processes,
18 pathogenic processes, or pharmacologic responses to a specific
19 therapeutic intervention, including known gene-drug interactions
20 for medications being considered for use or already being
21 administered. Biomarkers shall also include, but not be limited to,
22 gene mutations, characteristics of genes, or protein expression.

23 “Biomarker ²precision medical² testing” means the analysis of
24 tissue, blood, or other biospecimen for the presence of a biomarker.
25 Biomarker ²precision medical² testing includes^{2,2} but is not limited
26 to, single-analyte tests, multiplex panel tests, protein expression,
27 and whole exome, whole genome, and whole transcriptome
28 sequencing.

29

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