

S3098 (2R)

INTRODUCED BILL: (Includes sponsor(s) statement)	Yes	
REPRINT(S):	Yes	SCM 12/12/24 1R SBA 3/17/25 2R
TECHNICAL REVIEW OF BILL:	No	
COMMITTEE STATEMENT:	ASSEMBLY:	No
	SENATE:	Yes Commerce Budget & Appropriations

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, **may possibly** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT:	No	
LEGISLATIVE FISCAL ESTIMATE:	Yes	01/10/2025 03/26/2025

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

LEGISLATOR STATEMENT: Yes

FOLLOWING WERE PRINTED:

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REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

CL/MMcB

§1
C.17:48-6zz
§2
C.17:48A-7ww
§3
C.17:48E-35.50
§4
C.17B:26-2.1ss
§5
C.17B:27-46.1yy
§6
C.17B:27A-7.34
§7
C.17B:27A-19.38
§8
C.26:2J-4.51
§9
C.52:14-17.29nn
§10
C.52:14-17.46.6w
§11
C.30:4D-6y
§12
Note

P.L. 2025, CHAPTER 49, *approved April 23, 2025*
Assembly, No. 4163 (*Second Reprint*)

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

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
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 act², shall provide coverage for
15 biomarker precision medical² testing, as defined by subsection g. of
16 this section.

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 b. Biomarker ²precision medical² testing shall be covered for
2 the purposes of diagnosis, treatment, appropriate management, or
3 ongoing monitoring of a disease or condition², excluding
4 asymptomatic screening, to guide treatment decisions² of a subscriber
5 when the ²test is supported by medical and scientific evidence,
6 including, but not limited to efficacy and appropriateness of
7 biomarker precision medical testing for the diagnosis, treatment,
8 appropriate management, or guiding treatment decisions for a
9 subscriber's disease or condition is recognized by²:
- 10 (1) labeled indications for an FDA-approved or FDA-cleared
11 test;
- 12 (2) indicated tests for an FDA-approved drug;
- 13 (3) ²actions to address² warnings and precautions on FDA-
14 approved drug labels;
- 15 (4) Centers for Medicare and Medicaid Services National
16 Coverage Determinations or Medicare Administrative Contractor
17 Local Coverage Determinations; or
- 18 (5) nationally-recognized clinical practice guidelines ²and
19 consensus statements².
- 20 c. Coverage, pursuant to subsection b. of this section, shall be
21 provided in a manner that limits disruption, including multiple
22 biopsies or biospecimen samples, in the care of a subscriber.
- 23 d. (1) ¹Notwithstanding any other law, rule, or regulation
24 to the contrary, if If¹ utilization review is required, ¹a hospital
25 service corporation shall provide¹ a decision ¹shall be rendered on
26 a prior authorization request, and notice shall be sent to the
27 subscriber and the appropriate health care provider, and if the
28 request is made through a health care entity, to the health care
29 entity, within 72 hours for a non-urgent request or 24 hours for an
30 urgent request pursuant to the guidelines and timeframes set forth
31 in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.
- 32 (2) The subscriber and the treating health care provider or
33 treating health care entity prescribing biomarker ²precision medical²
34 testing for the subscriber shall have access to clear, readily
35 accessible, and conspicuous information on the process to submit an
36 appeal to an adverse determination.
- 37 e. The benefits shall be provided to the same extent as for any
38 other medical condition under the contract², including
39 determinations of clinical review criteria used for utilization review of
40 health care services along with copayment, deductible, and
41 coinsurance provisions².
- 42 f. The provisions of this section shall apply to all hospital
43 service corporation contracts in which the hospital service
44 corporation has reserved the right to change the premium.
- 45 g. As used in this section:

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

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

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

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

28
29 2. a. Each medical service corporation contract that provides
30 hospital or medical expense benefits and is delivered, issued,
31 executed, or renewed in this State pursuant to P.L.1940, c.74
32 (C.17:48A-1 et seq.) or is approved for issuance or renewal in this
33 State by the Commissioner of Banking and Insurance, on or after
34 the effective date of ²[P.L. , c. (C.) (pending before the
35 Legislature as this bill)] this act², shall provide coverage for
36 biomarker ²precision medical² testing, as defined by subsection g. of
37 this section.

38 b. Biomarker ²precision medical² testing shall be covered for
39 the purposes of diagnosis, treatment, appropriate management, or
40 ongoing monitoring of a disease or condition², excluding
41 asymptomatic screening, to guide treatment decisions² of a subscriber
42 when the ²[test is supported by medical and scientific evidence,
43 including, but not limited to] efficacy and appropriateness of
44 biomarker precision medical testing for the diagnosis, treatment,
45 appropriate management, or guiding treatment decisions for a
46 subscriber’s disease or condition is recognized by²:

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

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

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

4 (4) Centers for Medicare and Medicaid Services National
5 Coverage Determinations or Medicare Administrative Contractor
6 Local Coverage Determinations; or

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

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

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

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

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

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

34 g. As used in this section:

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

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

1 ¹["Consensus statement" means a statement developed by an
2 independent, multidisciplinary panel of experts utilizing a
3 transparent methodology and reporting structure and with a conflict
4 of interest policy. The statement shall be aimed at specific clinical
5 circumstances and be based on the best available evidence for the
6 purpose of optimizing the outcomes of clinical care.]¹

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

15
16 3. a. Each health service corporation contract that provides
17 hospital or medical expense benefits and is delivered, issued,
18 executed, or renewed in this State pursuant to P.L.1985, c.236
19 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this
20 State by the Commissioner of Banking and Insurance, on or after
21 the effective date of ²[P.L. , c. (C.) (pending before the
22 Legislature as this bill)] this act², shall provide coverage for
23 biomarker ²precision medical² testing, as defined by subsection g. of
24 this section.

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

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

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

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

38 (4) Centers for Medicare and Medicaid Services National
39 Coverage Determinations or Medicare Administrative Contractor
40 Local Coverage Determinations; or

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

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

1 d. (1) ¹【Notwithstanding any other law, rule, or regulation
2 to the contrary, if】 If¹ utilization review is required, ¹a health
3 service corporation shall provide¹ a decision ¹【shall be rendered on
4 a prior authorization request, and notice shall be sent to the
5 subscriber and the appropriate health care provider, and if the
6 request is made through a health care entity, to the health care
7 entity, within 72 hours for a non-urgent request or 24 hours for an
8 urgent request】 pursuant to the guidelines and timeframes set forth
9 in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

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

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

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

23 g. As used in this section:

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

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

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

43 “Nationally-recognized clinical practice guidelines” means
44 evidence-based clinical practice guidelines developed by
45 independent organizations or medical professional societies
46 utilizing a transparent methodology and reporting structure and with
47 a conflict of interest policy. The guidelines establish standards of

1 care informed by a systematic review of evidence and an
2 assessment of the benefits and risks of alternative care options and
3 include recommendations intended to optimize patient care.

4
5 4. a. Each individual health insurance policy that provides
6 hospital or medical expense benefits and is delivered, issued,
7 executed, or renewed in this State pursuant to chapter 26 of Title
8 17B of the New Jersey Statutes or is approved for issuance or
9 renewal in this State by the Commissioner of Banking and
10 Insurance, on or after the effective date of ²[P.L. , c. (C.)
11 (pending before the Legislature as this bill)] this act², shall provide
12 coverage for biomarker ²precision medical² testing, as defined by
13 subsection g. of this section.

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

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

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

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

27 (4) Centers for Medicare and Medicaid Services National
28 Coverage Determinations or Medicare Administrative Contractor
29 Local Coverage Determinations; or

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

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

35 d. (1) ¹[Notwithstanding any other law, rule, or regulation
36 to the contrary, if] If¹ utilization review is required, ¹a carrier shall
37 provide¹ a decision ¹[shall be rendered on a prior authorization
38 request, and notice shall be sent to the insured and the appropriate
39 health care provider, and if the request is made through a health
40 care entity, to the health care entity, within 72 hours for a non-
41 urgent request or 24 hours for an urgent request] pursuant to the
42 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-
43 55.1 et al.)¹.

44 (2) The insured and the treating health care provider or treating
45 health care entity prescribing biomarker ²precision medical² testing
46 for the insured shall have access to clear, readily accessible, and

1 conspicuous information on the process to submit an appeal to an
2 adverse determination.

3 e. The benefits shall be provided to the same extent as for any
4 other medical condition under the contract², including
5 determinations of clinical review criteria used for utilization review of
6 health care services along with copayment, deductible, and
7 coinsurance provisions².

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

11 g. As used in this section:

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

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

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

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

39

40 5. a. Each group health insurance policy that provides hospital
41 or medical expense benefits and is delivered, issued, executed, or
42 renewed in this State pursuant to chapter 27 of Title 17B of the New
43 Jersey Statutes or is approved for issuance or renewal in this State
44 by the Commissioner of Banking and Insurance, on or after the
45 effective date of ²**[P.L. , c. (C.) (pending before the**
46 **Legislature as this bill)]** this act², shall provide benefits for

- 1 biomarker ²precision medical² testing, as defined by subsection g. of
2 this section.
- 3 b. Biomarker ²precision medical² testing shall be covered for
4 the purposes of diagnosis, treatment, appropriate management, or
5 ongoing monitoring of a disease or condition², excluding
6 asymptomatic screening, to guide treatment decisions² of an insured
7 when the ²test is supported by medical and scientific evidence,
8 including, but not limited to efficacy and appropriateness of
9 biomarker precision medical testing for the diagnosis, treatment,
10 appropriate management, or guiding treatment decisions for an
11 insured's disease or condition is recognized by²:
- 12 (1) labeled indications for an FDA-approved or -cleared test;
13 (2) indicated tests for an FDA-approved drug;
14 (3) ²actions to address² warnings and precautions on FDA-
15 approved drug labels;
16 (4) Centers for Medicare and Medicaid Services National
17 Coverage Determinations or Medicare Administrative Contractor
18 Local Coverage Determinations; or
19 (5) nationally-recognized clinical practice guidelines ²and
20 consensus statements².
- 21 c. Coverage, pursuant to subsection b. of this section, shall be
22 provided in a manner that limits disruption, including multiple
23 biopsies or biospecimen samples, in the care of an insured.
- 24 d. (1) ¹Notwithstanding any other law, rule, or regulation
25 to the contrary, if ¹If utilization review is required, ¹an insurer
26 shall provide¹ a decision ¹shall be rendered on a prior
27 authorization request, and notice shall be sent to the insured and the
28 appropriate health care provider, and if the request is made through
29 a health care entity, to the health care entity, within 72 hours for a
30 non-urgent request or 24 hours for an urgent request ¹pursuant to
31 the guidelines and timeframes set forth in P.L.2023, c.296
32 (C.17B:30-55.1 et al.)¹.
- 33 (2) The insured and the treating health care provider or treating
34 health care entity prescribing biomarker ²precision medical² testing
35 for the insured shall have access to clear, readily accessible, and
36 conspicuous information on the process to submit an appeal to an
37 adverse determination.
- 38 e. The benefits shall be provided to the same extent as for any
39 other medical condition under the contract², including
40 determinations of clinical review criteria used for utilization review of
41 health care services along with copayment, deductible, and
42 coinsurance provisions².
- 43 f. The provisions of this section shall apply to all policies in
44 which the insurer has reserved the right to change the premium.
- 45 g. As used in this section:

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

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

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

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

28
29 6. a. Each individual health benefits plan that provides hospital
30 or medical expense benefits and is delivered, issued, executed, or
31 renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et
32 seq.) or is approved for issuance or renewal in this State by the
33 Commissioner of Banking and Insurance, on or after the effective
34 date of ²[P.L. , c. (C.) (pending before the Legislature as
35 this bill)] this act², shall provide benefits for biomarker ²precision
36 medical² testing, as defined by subsection g. of this section.

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

- 46 (1) labeled indications for an FDA-approved or -cleared test;
47 (2) indicated tests for an FDA-approved drug;

- 1 (3) ²actions to address² warnings and precautions on FDA-
2 approved drug labels;
- 3 (4) Centers for Medicare and Medicaid Services National
4 Coverage Determinations or Medicare Administrative Contractor
5 Local Coverage Determinations; or
- 6 (5) nationally-recognized clinical practice guidelines ²[and
7 consensus statements]².
- 8 c. Coverage, pursuant to subsection b. of this section, shall be
9 provided in a manner that limits disruption, including multiple
10 biopsies or biospecimen samples, in the care of a covered person.
- 11 d. (1) ¹[Notwithstanding any other law, rule, or regulation
12 to the contrary, if] ¹If utilization review is required, ¹a carrier shall
13 provide¹ a decision ¹[shall be rendered on a prior authorization
14 request, and notice shall be sent to the covered person and the
15 appropriate health care provider, and if the request is made through
16 a health care entity, to the health care entity, within 72 hours for a
17 non-urgent request or 24 hours for an urgent request] pursuant to
18 the guidelines and timeframes set forth in P.L.2023, c.296
19 (C.17B:30-55.1 et al.)¹.
- 20 (2) The covered person and the treating health care provider or
21 treating health care entity prescribing biomarker ²precision medical²
22 testing for the covered person shall have access to clear, readily
23 accessible, and conspicuous information on the process to submit an
24 appeal to an adverse determination.
- 25 e. The benefits shall be provided to the same extent as for any
26 other medical condition under the health benefits plan², including
27 determinations of clinical review criteria used for utilization review of
28 health care services along with copayment, deductible, and
29 coinsurance provisions².
- 30 f. The provisions of this section shall apply to all health
31 benefits plans in which the carrier has reserved the right to change
32 the premium.
- 33 g. As used in this section:
- 34 “Biomarker” means a characteristic that is objectively measured
35 and evaluated as an indicator of normal biological processes,
36 pathogenic processes, or pharmacologic responses to a specific
37 therapeutic intervention, including known gene-drug interactions
38 for medications being considered for use or already being
39 administered. Biomarkers shall also include, but not be limited to,
40 gene mutations, characteristics of genes, or protein expression.
- 41 “Biomarker ²precision medical² testing” means the analysis of
42 tissue, blood, or other biospecimen for the presence of a biomarker.
43 Biomarker ²precision medical² testing includes^{2, 2} but is not limited
44 to, single-analyte tests, multiplex panel tests, protein expression,
45 and whole exome, whole genome, and whole transcriptome
46 sequencing.

1 ¹["Consensus statement" means a statement developed by an
2 independent, multidisciplinary panel of experts utilizing a
3 transparent methodology and reporting structure and with a conflict
4 of interest policy. The statement shall be aimed at specific clinical
5 circumstances and be based on the best available evidence for the
6 purpose of optimizing the outcomes of clinical care.]¹

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

15
16 7. a. Each small employer health benefits plan that provides
17 hospital or medical expense benefits and is delivered, issued,
18 executed, or renewed in this State pursuant to P.L.1992, c.162
19 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in
20 this State by the Commissioner of Banking and Insurance, on or
21 after the effective date of ²[P.L. , c. (C.) (pending before
22 the Legislature as this bill)] this act², shall provide benefits for
23 biomarker ²precision medical² testing, as defined by subsection g. of
24 this section.

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

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

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

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

38 (4) Centers for Medicare and Medicaid Services National
39 Coverage Determinations or Medicare Administrative Contractor
40 Local Coverage Determinations; or

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

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

1 d. (1) ¹【Notwithstanding any other law, rule, or regulation
2 to the contrary, if】 If¹ utilization review is required, ¹a carrier shall
3 provide¹ a decision ¹【shall be rendered on a prior authorization
4 request, and notice shall be sent to the covered person and the
5 appropriate health care provider, and if the request is made through
6 a health care entity, to the health care entity, within 72 hours for a
7 non-urgent request or 24 hours for an urgent request】 pursuant to
8 the guidelines and timeframes set forth in P.L.2023, c.296
9 (C.17B:30-55.1 et al.)¹.

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

15 e. The benefits shall be provided to the same extent as for any
16 other medical condition under the health benefits plan², including
17 determinations of clinical review criteria used for utilization review of
18 health care services along with copayment, deductible, and
19 coinsurance provisions².

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

23 g. As used in this section:

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

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

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

43 “Nationally-recognized clinical practice guidelines” means
44 evidence-based clinical practice guidelines developed by
45 independent organizations or medical professional societies
46 utilizing a transparent methodology and reporting structure and with
47 a conflict of interest policy. The guidelines establish standards of

1 care informed by a systematic review of evidence and an
2 assessment of the benefits and risks of alternative care options and
3 include recommendations intended to optimize patient care.

4
5 8. a. Each health maintenance organization contract for health
6 care services that is delivered, issued, executed, or renewed in this
7 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved
8 for issuance or renewal in this State by the Commissioner of
9 Banking and Insurance, on or after the effective date of
10 ²[P.L. , c. (C.) (pending before the Legislature as this
11 bill)] this act², shall provide health care services for biomarker
12 precision medical² testing, as defined by subsection g. of this
13 section.

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

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

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

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

27 (4) Centers for Medicare and Medicaid Services National
28 Coverage Determinations or Medicare Administrative Contractor
29 Local Coverage Determinations; or

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

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

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

44 (2) The enrollee and the treating health care provider or treating
45 health care entity prescribing biomarker precision medical² testing
46 for the enrollee shall have access to clear, readily accessible, and

1 conspicuous information on the process to submit an appeal to an
2 adverse determination.

3 e. The health care services shall be provided to the same extent
4 as for any other medical condition under the contract², including
5 determinations of clinical review criteria used for utilization review of
6 health care services along with copayment, deductible, and
7 coinsurance provisions².

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

12 g. As used in this section:

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

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

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

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

40

41 9. a. The State Health Benefits Commission shall ensure that
42 every contract providing hospital or medical expense benefits,
43 which is purchased by the commission on or after the effective date
44 of ²【P.L. , c. (C.) (pending before the Legislature as this
45 bill)】 this act², provides coverage for biomarker ²precision medical²
46 testing, as defined by subsection e. of this section.

1 b. Biomarker ²precision medical² testing shall be covered for
2 the purposes of diagnosis, treatment, appropriate management, or
3 ongoing monitoring of a disease or condition², excluding
4 asymptomatic screening, to guide treatment decisions² of a covered
5 person when the ²test is supported by medical and scientific
6 evidence, including, but not limited to ²efficacy and appropriateness
7 of biomarker precision medical testing for the diagnosis, treatment,
8 appropriate management, or guiding treatment decisions for a covered
9 person's disease or condition is recognized by²:

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

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

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

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

35 e. As used in this section:

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

43 “Biomarker ²precision medical² testing” means the analysis of
44 tissue, blood, or other biospecimen for the presence of a biomarker.
45 Biomarker ²precision medical² testing includes^{2,2} but is not limited
46 to, single-analyte tests, multiplex panel tests, protein expression,

1 and whole exome, whole genome, and whole transcriptome
2 sequencing.

3 ¹["Consensus statement" means a statement developed by an
4 independent, multidisciplinary panel of experts utilizing a
5 transparent methodology and reporting structure and with a conflict
6 of interest policy. The statement shall be aimed at specific clinical
7 circumstances and be based on the best available evidence for the
8 purpose of optimizing the outcomes of clinical care.]¹

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

17

18 10. a. The School Employees' Health Benefits Commission
19 shall ensure that every contract providing hospital or medical
20 expense benefits, which is purchased by the commission on or after
21 the effective date of ²[P.L. , c. (C.) (pending before the
22 Legislature as this bill)] this act², provides coverage for biomarker
23 ²precision medical² testing, as defined by subsection e. of this
24 section.

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

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

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

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

38 (4) Centers for Medicare and Medicaid Services National
39 Coverage Determinations or Medicare Administrative Contractor
40 Local Coverage Determinations; or

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

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

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

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

14 e. As used in this section:

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

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

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

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

42
43 11. a. Notwithstanding any State law or regulation to the
44 contrary, the Department of Human Services shall ensure that
45 expenses incurred for biomarker ²precision medical² testing shall be
46 provided with no cost-sharing to persons served under the Medicaid

1 program, established pursuant to P.L.1968, c.413 (C.30:4D-
2 1 et seq.).

3 b. Biomarker ²precision medical² testing shall be covered for
4 the purposes of diagnosis, treatment, appropriate management, or
5 ongoing monitoring of a disease or condition², excluding
6 asymptomatic screening, to guide treatment decisions² of an
7 individual when the ²test is supported by medical and scientific
8 evidence, including, but not limited to ²efficacy and appropriateness
9 of biomarker precision medical testing for the diagnosis, treatment,
10 appropriate management, or guiding treatment decisions for an
11 individual's disease or condition is recognized by²:

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

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

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

16 (4) Centers for Medicare and Medicaid Services National
17 Coverage Determinations or Medicare Administrative Contractor
18 Local Coverage Determinations; or

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

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

24 d. If the Division of Medical Assistance and Health Services in
25 the Department of Human Services contracts with a third-party
26 entity to deliver biomarker ²precision medical² testing services
27 pursuant to this section to beneficiaries under the Medicaid
28 program, the third-party entity shall provide biomarker ²precision
29 medical² testing at the same scope, duration and frequency as the
30 Medicaid program otherwise provides to individuals.

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

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

45 f. As used in this section:

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

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

14

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

18

19

20

21

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

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.

ASSEMBLY, No. 4163

STATE OF NEW JERSEY 221st LEGISLATURE

INTRODUCED APRIL 8, 2024

Sponsored by:

Assemblywoman SHAVONDA E. SUMTER

District 35 (Bergen and Passaic)

Assemblyman GARY S. SCHAER

District 36 (Bergen and Passaic)

Assemblywoman SHAMA A. HAIDER

District 37 (Bergen)

Co-Sponsored by:

Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin,

Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn,

Assemblymen Conaway, DePhillips, Calabrese, Barlas, Assemblywoman

Speight, Assemblymen Spearman, DiMaio, Assemblywoman Peterpaul,

Assemblymen McClellan, Simonsen, Hutchison, Verrelli, Assemblywoman

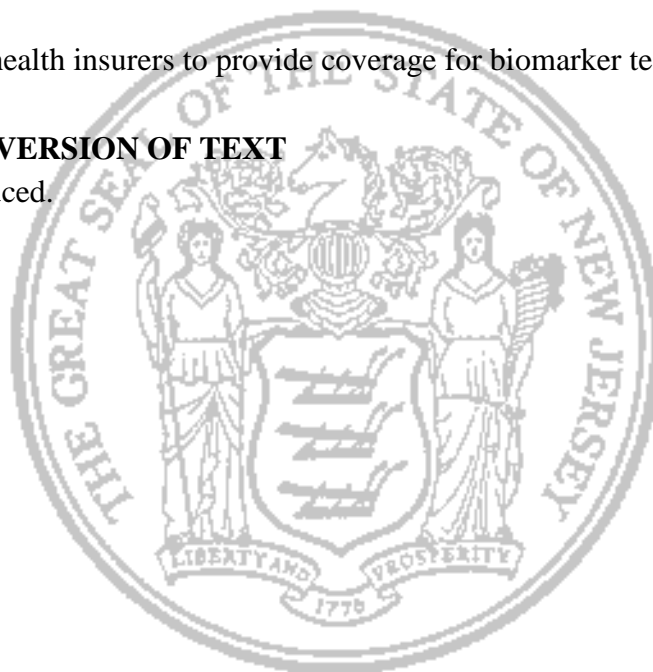
Park and Assemblyman Stanley

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As introduced.



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

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

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
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 State
12 by the Commissioner of Banking and Insurance, on or after the
13 effective date of P.L. , c. (C.) (pending before the Legislature
14 as this bill), shall provide coverage for biomarker testing, as defined
15 by subsection g. of this section.

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

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

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

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

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

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

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

1 g. As used in this section:

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

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

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

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

28

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

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

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

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

44 (3) warnings and precautions on FDA-approved drug labels;

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

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

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 a subscriber.

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

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

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

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

23 g. As used in this section:

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

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

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

42 “Nationally-recognized clinical practice guidelines” means
43 evidence-based clinical practice guidelines developed by
44 independent organizations or medical professional societies utilizing
45 a transparent methodology and reporting structure and with a conflict
46 of interest policy. The guidelines establish standards of care
47 informed by a systematic review of evidence and an assessment of

1 the benefits and risks of alternative care options and include
2 recommendations intended to optimize patient care.

3

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

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

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

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

19 (3) warnings and precautions on FDA-approved drug labels;

20 (4) Centers for Medicare and Medicaid Services National
21 Coverage Determinations or Medicare Administrative Contractor
22 Local Coverage Determinations; or

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

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

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

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

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

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

45 g. As used in this section:

46 "Biomarker" means a characteristic that is objectively measured
47 and evaluated as an indicator of normal biological processes,
48 pathogenic processes, or pharmacologic responses to a specific

1 therapeutic intervention, including known gene-drug interactions for
2 medications being considered for use or already being administered.
3 Biomarkers shall also include, but not be limited to, gene mutations,
4 characteristics of genes, or protein expression.

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

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

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

24

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

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

- 38 (1) labeled indications for an FDA-approved or -cleared test;
39 (2) indicated tests for an FDA-approved drug;
40 (3) warnings and precautions on FDA-approved drug labels;
41 (4) Centers for Medicare and Medicaid Services National
42 Coverage Determinations or Medicare Administrative Contractor
43 Local Coverage Determinations; or
44 (5) nationally-recognized clinical practice guidelines and
45 consensus statements.

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

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

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

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

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

17 g. As used in this section:

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

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

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

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

44
45 5. a. Each group health insurance policy that provides hospital
46 or medical expense benefits and is delivered, issued, executed, or
47 renewed in this State pursuant to chapter 27 of Title 17B of the New
48 Jersey Statutes or is approved for issuance or renewal in this State by

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

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

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

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

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

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

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

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

35 g. As used in this section:

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

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

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

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

15

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

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

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

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

31 (3) warnings and precautions on FDA-approved drug labels;

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

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

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

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

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

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

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

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

9 g. As used in this section:

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

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

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

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

36

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

45 b. Biomarker testing shall be covered for the purposes of
46 diagnosis, treatment, appropriate management, or ongoing
47 monitoring of a disease or condition of a covered person when the

1 test is supported by medical and scientific evidence, including, but
2 not limited to:

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

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

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

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

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

28 f. The provisions of this section shall apply to all health benefits
29 plans in which the carrier has reserved the right to change the
30 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 for
36 medications being considered for use or already being administered.
37 Biomarkers shall also include, but not be limited to, gene mutations,
38 characteristics of genes, or protein expression.

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

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

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

11

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

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

- 25 (1) labeled indications for an FDA-approved or -cleared test;
26 (2) indicated tests for an FDA-approved drug;
27 (3) warnings and precautions on FDA-approved drug labels;
28 (4) Centers for Medicare and Medicaid Services National
29 Coverage Determinations or Medicare Administrative Contractor
30 Local Coverage Determinations; or
31 (5) nationally-recognized clinical practice guidelines and
32 consensus statements.

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

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

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

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

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

5 g. As used in this section:

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

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

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

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

32

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

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

- 44 (1) labeled indications for an FDA-approved or -cleared test;
45 (2) indicated tests for an FDA-approved drug;
46 (3) warnings and precautions on FDA-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 and
5 consensus statements.

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 a covered person.

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

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

21 e. As used in this section:

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

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

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

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

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

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

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

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

14 (3) warnings and precautions on FDA-approved drug labels;

15 (4) Centers for Medicare and Medicaid Services National
16 Coverage Determinations or Medicare Administrative Contractor
17 Local Coverage Determinations; or

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

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

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

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

35 e. As used in this section:

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

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

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

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

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

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

- 26 (1) labeled indications for an FDA-approved or -cleared test;
27 (2) indicated tests for an FDA-approved drug;
28 (3) warnings and precautions on FDA-approved drug labels;
29 (4) Centers for Medicare and Medicaid Services National
30 Coverage Determinations or Medicare Administrative Contractor
31 Local Coverage Determinations; or
32 (5) nationally-recognized clinical practice guidelines and
33 consensus statements.

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

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

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

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

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

8 f. As used in this section:

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

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

21

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

25

26

27

STATEMENT

28

29 This bill requires health insurers to cover biomarker testing.
30 Under the bill, health insurance carriers (including health service
31 corporations, hospital service corporations, medical service
32 corporations, commercial individual and group health insurers,
33 health maintenance organizations, entities contracted to administer
34 health benefits in connection with the State Health Benefits Program
35 and School Employees’ Health Benefits Program, and Medicaid) are
36 to cover testing for the purposes of diagnosis, treatment, appropriate
37 management, or ongoing monitoring of an individual’s disease or
38 condition when the test is supported by medical and scientific
39 evidence. The evidence includes, but is not limited to: (1) labeled
40 indications for an FDA-approved or -cleared test; (2) indicated
41 tests for an FDA-approved drug; (3) warnings and precautions
42 on FDA-approved drug labels; (4) Centers for Medicare and
43 Medicaid Services National Coverage Determinations or Medicare
44 Administrative Contractor Local Coverage Determinations; or
45 (5) Nationally recognized clinical practice guidelines and
46 consensus statements. Coverage is to be provided in a manner that
47 limits disruption, including multiple biopsies or biospecimen

A4163 SUMTER, SCHAER

18

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

[First 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 testing.

CURRENT VERSION OF TEXT

As reported by the Assembly Financial Institutions and Insurance Committee on October 24, 2024, with amendments.

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

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

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
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 P.L. , c. (C.) (pending before the
14 Legislature as this bill), shall provide coverage for biomarker
15 testing, as defined by subsection g. of this section.

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

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

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

24 (3) warnings and precautions on FDA-approved drug labels;

25 (4) Centers for Medicare and Medicaid Services National
26 Coverage Determinations or Medicare Administrative Contractor
27 Local Coverage Determinations; or

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

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

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

42 (2) The subscriber and the treating health care provider or
43 treating health care entity prescribing biomarker testing for the
44 subscriber shall have access to clear, readily accessible, and

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.

1 conspicuous information on the process to submit an appeal to an
2 adverse determination.

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

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

8 g. As used in this section:

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

16 “Biomarker testing” means the analysis of tissue, blood, or other
17 biospecimen for the presence of a biomarker. Biomarker testing
18 includes but is not limited to, single-analyte tests, multiplex panel
19 tests, protein expression, and whole exome, whole genome, and
20 whole transcriptome 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 2. a. Each medical 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.1940, c.74
39 (C.17:48A-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 P.L. , c. (C.) (pending before the
42 Legislature as this bill), shall provide coverage for biomarker
43 testing, as defined by subsection g. of this section.

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

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

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

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

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

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

28 f. The provisions of this section shall apply to all medical
29 service corporation contracts in which the medical service
30 corporation has reserved the right to change 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 testing” means the analysis of tissue, blood, or other
40 biospecimen for the presence of a biomarker. Biomarker testing
41 includes but is not limited to, single-analyte tests, multiplex panel
42 tests, protein expression, and whole exome, whole genome, and
43 whole transcriptome sequencing.

44 ¹【“Consensus statement” means a statement developed by an
45 independent, multidisciplinary panel of experts utilizing a
46 transparent methodology and reporting structure and with a conflict
47 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 3. a. Each health service corporation contract that provides
13 hospital or medical expense benefits and is delivered, issued,
14 executed, or renewed in this State pursuant to P.L.1985, c.236
15 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this
16 State by the Commissioner of Banking and Insurance, on or after
17 the effective date of P.L. , c. (C.) (pending before the
18 Legislature as this bill), shall provide coverage for biomarker
19 testing, as defined by subsection g. of this section.

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

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

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

27 (3) warnings and precautions on FDA-approved drug labels;

28 (4) Centers for Medicare and Medicaid Services National
29 Coverage Determinations or Medicare Administrative Contractor
30 Local Coverage Determinations; or

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

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

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

45 (2) The subscriber and the treating health care provider or
46 treating health care entity prescribing biomarker testing for the
47 subscriber shall have access to clear, readily accessible, and

1 conspicuous information on the process to submit an appeal to an
2 adverse determination.

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

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

8 g. As used in this section:

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

16 “Biomarker testing” means the analysis of tissue, blood, or other
17 biospecimen for the presence of a biomarker. Biomarker testing
18 includes but is not limited to, single-analyte tests, multiplex panel
19 tests, protein expression, and whole exome, whole genome, and
20 whole transcriptome 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 4. a. Each individual health insurance policy that provides
37 hospital or medical expense benefits and is delivered, issued,
38 executed, or renewed in this State pursuant to chapter 26 of Title
39 17B of the New Jersey Statutes or is approved for issuance or
40 renewal in this State by the Commissioner of Banking and
41 Insurance, on or after the effective date of P.L. , c. (C.)
42 (pending before the Legislature as this bill), shall provide coverage
43 for biomarker testing, as defined by subsection g. of this section.

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

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

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

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

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

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

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

44 ¹“Consensus statement” means a statement developed by an
45 independent, multidisciplinary panel of experts utilizing a
46 transparent methodology and reporting structure and with a conflict
47 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 5. a. Each group health insurance policy that provides hospital
13 or medical expense benefits and is delivered, issued, executed, or
14 renewed in this State pursuant to chapter 27 of Title 17B of the New
15 Jersey Statutes or is approved for issuance or renewal in this State
16 by the Commissioner of Banking and Insurance, on or after the
17 effective date of P.L. , c. (C.) (pending before the
18 Legislature as this bill), shall provide benefits for biomarker testing,
19 as defined by subsection g. of this section.

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

- 25 (1) labeled indications for an FDA-approved or -cleared test;
26 (2) indicated tests for an FDA-approved drug;
27 (3) warnings and precautions on FDA-approved drug labels;
28 (4) Centers for Medicare and Medicaid Services National
29 Coverage Determinations or Medicare Administrative Contractor
30 Local Coverage Determinations; or
31 (5) nationally-recognized clinical practice guidelines and
32 consensus statements.

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

36 d. (1) ¹【Notwithstanding any other law, rule, or regulation
37 to the contrary, if】 If¹ utilization review is required, an insurer
38 shall provide¹ a decision ¹【shall be rendered on a prior
39 authorization request, and notice shall be sent to the insured and the
40 appropriate health care provider, and if the request is made through
41 a health care entity, to the health care entity, within 72 hours for a
42 non-urgent request or 24 hours for an urgent request】 pursuant to
43 the guidelines and timeframes set forth in P.L.2023, c.296
44 (C.17B:30-55.1 et al.)¹.

45 (2) The insured and the treating health care provider or treating
46 health care entity prescribing biomarker testing for the insured shall
47 have access to clear, readily accessible, and conspicuous

1 information on the process to submit an appeal to an adverse
2 determination.

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

5 f. The provisions of this section shall apply to all policies in
6 which the insurer 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 testing” means the analysis of tissue, blood, or other
16 biospecimen for the presence of a biomarker. Biomarker testing
17 includes but is not limited to, single-analyte tests, multiplex panel
18 tests, protein expression, and whole exome, whole genome, and
19 whole transcriptome 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 6. a. Each individual health benefits plan that provides hospital
36 or medical expense benefits and is delivered, issued, executed, or
37 renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et
38 seq.) or is approved for issuance or renewal in this State by the
39 Commissioner of Banking and Insurance, on or after the effective
40 date of P.L. , c. (C.) (pending before the Legislature as this
41 bill), shall provide benefits for biomarker testing, as defined by
42 subsection g. of this section.

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

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

- 1 (2) indicated tests for an FDA-approved drug;
- 2 (3) warnings and precautions on FDA-approved drug labels;
- 3 (4) Centers for Medicare and Medicaid Services National
- 4 Coverage Determinations or Medicare Administrative Contractor
- 5 Local Coverage Determinations; or
- 6 (5) nationally-recognized clinical practice guidelines and
- 7 consensus statements.

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

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

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

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

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

30 g. As used in this section:

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

38 “Biomarker testing” means the analysis of tissue, blood, or other
39 biospecimen for the presence of a biomarker. Biomarker testing
40 includes but is not limited to, single-analyte tests, multiplex panel
41 tests, protein expression, and whole exome, whole genome, and
42 whole transcriptome 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 7. a. Each small employer health benefits plan that provides
13 hospital or medical expense benefits and is delivered, issued,
14 executed, or renewed in this State pursuant to P.L.1992, c.162
15 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in
16 this State by the Commissioner of Banking and Insurance, on or
17 after the effective date of P.L. , c. (C.) (pending before the
18 Legislature as this bill), shall provide benefits for biomarker testing,
19 as defined by subsection g. of this section.

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

- 25 (1) labeled indications for an FDA-approved or -cleared test;
26 (2) indicated tests for an FDA-approved drug;
27 (3) warnings and precautions on FDA-approved drug labels;
28 (4) Centers for Medicare and Medicaid Services National
29 Coverage Determinations or Medicare Administrative Contractor
30 Local Coverage Determinations; or
31 (5) nationally-recognized clinical practice guidelines and
32 consensus statements.

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

36 d. (1) ¹【Notwithstanding any other law, rule, or regulation
37 to the contrary, if】 if¹ utilization review is required, ¹a carrier shall
38 provide¹ a decision ¹【shall be rendered on a prior authorization
39 request, and notice shall be sent to the covered person and the
40 appropriate health care provider, and if the request is made through
41 a health care entity, to the health care entity, within 72 hours for a
42 non-urgent request or 24 hours for an urgent request】 pursuant to
43 the guidelines and timeframes set forth in P.L.2023, c.296
44 (C.17B:30-55.1 et al.)¹.

45 (2) The covered person and the treating health care provider or
46 treating health care entity prescribing biomarker testing for the
47 covered person shall have access to clear, readily accessible, and

1 conspicuous information on the process to submit an appeal to an
2 adverse determination.

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

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

8 g. As used in this section:

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

16 “Biomarker testing” means the analysis of tissue, blood, or other
17 biospecimen for the presence of a biomarker. Biomarker testing
18 includes but is not limited to, single-analyte tests, multiplex panel
19 tests, protein expression, and whole exome, whole genome, and
20 whole transcriptome 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 8. a. Each health maintenance organization contract for health
37 care services that is delivered, issued, executed, or renewed in this
38 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved
39 for issuance or renewal in this State by the Commissioner of
40 Banking and Insurance, on or after the effective date of P.L. ,
41 c. (C.) (pending before the Legislature as this bill), shall
42 provide health care services for biomarker testing, as defined by
43 subsection g. of this section.

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

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

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

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

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

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

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

32 g. As used in this section:

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

40 “Biomarker testing” means the analysis of tissue, blood, or other
41 biospecimen for the presence of a biomarker. Biomarker testing
42 includes but is not limited to, single-analyte tests, multiplex panel
43 tests, protein expression, and whole exome, whole genome, and
44 whole transcriptome 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 9. a. The State Health Benefits Commission shall ensure that
14 every contract providing hospital or medical expense benefits,
15 which is purchased by the commission on or after the effective date
16 of P.L. , c. (C.) (pending before the Legislature as this
17 bill), provides coverage for biomarker testing, as defined by
18 subsection e. of this section.

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

- 24 (1) labeled indications for an FDA-approved or -cleared test;
25 (2) indicated tests for an FDA-approved drug;
26 (3) warnings and precautions on FDA-approved drug labels;
27 (4) Centers for Medicare and Medicaid Services National
28 Coverage Determinations or Medicare Administrative Contractor
29 Local Coverage Determinations; or
30 (5) nationally-recognized clinical practice guidelines and
31 consensus statements.

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

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

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

1 e. As used in this section:

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

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

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

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

28
29 10. a. The School Employees’ Health Benefits Commission
30 shall ensure that every contract providing hospital or medical
31 expense benefits, which is purchased by the commission on or after
32 the effective date of P.L. , c. (C.) (pending before the
33 Legislature as this bill), provides coverage for biomarker testing, as
34 defined by subsection e. of this section.

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

- 40 (1) labeled indications for an FDA-approved or -cleared test;
- 41 (2) indicated tests for an FDA-approved drug;
- 42 (3) warnings and precautions on FDA-approved drug labels;
- 43 (4) Centers for Medicare and Medicaid Services National
44 Coverage Determinations or Medicare Administrative Contractor
45 Local Coverage Determinations; or
- 46 (5) nationally-recognized clinical practice guidelines and
47 consensus statements.

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

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

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

17 e. As used in this section:

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

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

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

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

44
45 11. a. Notwithstanding any State law or regulation to the
46 contrary, the Department of Human Services shall ensure that
47 expenses incurred for biomarker testing shall be provided with no

1 cost-sharing to persons served under the Medicaid program,
2 established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

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

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

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

10 (3) warnings and precautions on FDA-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 and
15 consensus statements.

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 an individual.

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

26 e. (1) ¹~~Notwithstanding any other law, rule, or regulation~~
27 ~~to the contrary, if~~ ¹~~If~~ utilization review is required, a decision
28 ¹~~shall be rendered on a prior authorization request, and notice be~~
29 ~~sent to an individual, the appropriate health care provider, and, if~~
30 ~~necessary, the requisite health care entity if the request for prior~~
31 ~~authorization was submitted through the entity, within 72 hours for~~
32 ~~a non-urgent request or 24 hours for an urgent request~~ shall be
33 provided pursuant to the guidelines and timeframes set forth in
34 P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

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

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

6

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

[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.

4
 5 **BE IT ENACTED** by the Senate and General Assembly of the State
 6 of New Jersey:

7
 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 act², 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]** If¹ 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) ²actions 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] If¹ 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] pursuant 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 ²**precision medical**² 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 provisions**².

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 ²**precision medical**² testing” means the analysis of
27 tissue, blood, or other biospecimen for the presence of a biomarker.
28 Biomarker ²**precision medical**² 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 ²[test is supported by medical and scientific
2 evidence, including, but not limited to] 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 ²[and
14 consensus statements]².

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) ¹[Notwithstanding any other law, rule, or regulation
19 to the contrary, if] If¹ utilization review is required, ¹a carrier shall
20 provide¹ a decision ¹[shall 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] 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 utilization 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.

1 (2) The covered person and the treating health care provider or
2 treating health care entity prescribing biomarker ²precision medical²
3 testing to the covered person shall have access to clear, readily
4 accessible, and conspicuous information on the process to submit an
5 appeal to an adverse determination.

6 e. 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 10. a. The School Employees’ Health Benefits Commission
36 shall ensure that every contract providing hospital or medical
37 expense benefits, which is purchased by the commission on or after
38 the effective date of ²[P.L. , c. (C.) (pending before the
39 Legislature as this bill)] this act², provides coverage for biomarker
40 ²precision medical² testing, as defined by subsection e. of this
41 section.

42 b. Biomarker ²precision medical² testing shall be covered for
43 the purposes of diagnosis, treatment, appropriate management, or
44 ongoing monitoring of a disease or condition², excluding
45 asymptomatic screening, to guide treatment decisions² of a covered
46 person when the ²[test is supported by medical and scientific
47 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) actions 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 ²[and
12 consensus statements]².

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) ¹[Notwithstanding any other law, rule, or regulation
17 to the contrary, if] If¹ utilization review is required, a decision shall
18 be rendered ¹[on 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] pursuant 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 precision 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 precision medical² testing” means the analysis of
38 tissue, blood, or other biospecimen for the presence of a biomarker.
39 Biomarker precision 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 precision 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 precision 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) actions 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 precision medical² testing services
42 pursuant to this section to beneficiaries under the Medicaid
43 program, the third-party entity shall provide biomarker precision
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.

ASSEMBLY FINANCIAL INSTITUTIONS AND INSURANCE
COMMITTEE

STATEMENT TO
ASSEMBLY, No. 4163

with committee amendments

STATE OF NEW JERSEY

DATED: OCTOBER 24, 2024

The Assembly Financial Institutions and Insurance Committee reports favorably and with committee amendments Assembly Bill No. 4163.

As amended, this bill requires health insurers to cover biomarker testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The evidence includes, but is not limited to: (1) labeled indications for an FDA-approved or -cleared test; (2) indicated tests for an FDA-approved drug; (3) warnings and precautions on FDA-approved drug labels; (4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or (5) Nationally recognized clinical practice guidelines and consensus statements. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

The bill also stipulates that utilization review decisions concerning coverage provided under the bill are to be made in accordance with guidelines and timeframes already present in current law.

COMMITTEE AMENDMENTS:

The committee amended the bill to:

(1) require carriers to provide biomarker testing to covered persons pursuant to guidelines and timeframes set forth in the "Ensuring Transparency in Prior Authorization Act," if utilization review is required;

(2) remove the definition of "consensus statement"; and

(3) make a technical correction.

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

[First Reprint]

ASSEMBLY, No. 4163

STATE OF NEW JERSEY

DATED: DECEMBER 16, 2024

The Assembly Appropriations Committee reports favorably Assembly Bill No. 4163 (1R).

This bill requires health insurers to cover biomarker testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The evidence includes, but is not limited to: (1) labeled indications for an FDA-approved or -cleared test; (2) indicated tests for an FDA-approved drug; (3) warnings and precautions on FDA-approved drug labels; (4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or (5) nationally recognized clinical practice guidelines and consensus statements. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

The bill also stipulates that utilization review decisions concerning coverage provided under the bill are to be made in accordance with guidelines and timeframes already present in current law.

FISCAL IMPACT:

The Office of Legislative Services (OLS) estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual indeterminate expenditures increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in an annual

indeterminate expenditure impact for GetCoveredNJ, the State-based health insurance marketplace.

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual net expenditures increases of \$372,000 to \$670,000 for the NJ FamilyCare program, which encompasses the State Medicaid program and the Children's Health Insurance Program.

STATEMENT TO
[First Reprint]
ASSEMBLY, No. 4163

with Senate Floor Amendments
(Proposed by Senator GOPAL)

ADOPTED: MARCH 24, 2025

This floor amendment:

- (1) modifies the coverage to be provided by health insurers under the bill to include coverage for biomarker precision medical testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition;
- (2) clarifies the circumstances under which biomarker precision medical testing is required to be covered;
- (3) adds language requiring certain insurers to provide coverage for biomarker precision medical testing to the same extent as for other medical conditions, including clinical review criteria used for utilization review of health care services and copayment, deductible, and coinsurance provisions; and
- (4) makes technical changes.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

ASSEMBLY, No. 4163

STATE OF NEW JERSEY 221st LEGISLATURE

DATED: DECEMBER 13, 2024

SUMMARY

- Synopsis:** Requires health insurers to provide coverage for biomarker testing.
- Type of Impact:** Annual expenditure increase to the State and participating local entities.
- Agencies Affected:** Division of Pensions and Benefits in the Department of the Treasury; Department of Banking and Insurance; Department of Human Services; Local Governments; School Districts.

Office of Legislative Services Estimate

Fiscal Impact	<u>Annual</u>
State Expenditure Increase for SHBP-State	Indeterminate
Local Expenditure Increase for SHBP-Local and SEHBP	Indeterminate
State Expenditure Impact for GetCoveredNJ	Indeterminate
Net State Expenditure Increase for NJ FamilyCare	\$372,000 to \$670,000

- The Office of Legislative Services (OLS) estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in an annual indeterminate expenditure impact for GetCoveredNJ, the State-based health insurance marketplace.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual net expenditure increases of \$372,000 to \$670,000 for the NJ FamilyCare program, which encompasses the State Medicaid program and the Children's Health Insurance Program.

BILL DESCRIPTION

This bill requires health insurers, including the State Health Benefits Program, the School Employees' Health Benefits Program, and the State Medicaid program, to provide coverage for biomarker testing. Under the bill, testing includes diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The bill also states that utilization review decisions regarding coverage are to be made in accordance with current statutory guidelines and timeframes.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

If large group self-insured plans in the national commercial market serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from a 2022 landscape analysis prepared by Milliman, a consultancy, suggest that requiring health insurance carriers to provide coverage for biomarker testing would increase annual State expenditures by approximately \$0.5 million and collective annual expenditures of participating local entities by approximately \$0.9 million. If self-insured plans that provide coverage to State and local employees through the Group Insurance Commission in Massachusetts serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from an April 2024 analysis by BerryDunn, a consulting firm, suggest that requiring health insurance carriers to provide coverage for biomarker testing would increase annual State expenditures by approximately \$2.5 million and collective annual expenditures of participating local entities by approximately \$4.1 million.

The OLS is unable to determine the number of additional diagnostic, treatment, management, or monitoring procedures that would be newly eligible for coverage under the State Health Benefits Program or the School Employees' Health Benefits Program under the bill's provisions. Additionally, the OLS does not know the employer/employee cost share arrangements that would determine the State and local cost increases for the expanded number of covered procedures. Furthermore, the OLS does not know the utilization review or prior authorization requirements that would impact the distribution and cost of additional procedures provided to covered persons under current or future health benefits contracts negotiated by the State Health Benefits Program and the School Employees' Health Benefits Program and their insurers.

In the absence of this information, the OLS concludes that the bill's provisions will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in an annual indeterminate expenditure impact for Get Covered New Jersey, the State-based health insurance marketplace. New Jersey Health Plan Savings or State-paid subsidies on health insurance premiums for policies offered through the State Marketplace are available to certain individuals and households who meet certain income requirements. If requiring coverage for biomarker testing increases the payment needed to subsidize healthcare services for this population, State costs will increase. There are no data regarding the current level of testing, nor any predictive data on the prevalence of this testing in the future. Since there are multiple types of testing available, each with a different cost baseline, it is not possible to predict with any certainty how the cost structure for each test may change in the future or predict the proportional share each particular test will have in the overall patient pool in the State.

The OLS concludes that State costs will increase anywhere from \$1.1 million to \$2.0 million annually for the NJ FamilyCare program to cover biomarker testing, when supported by specific medical and scientific evidence, as required under the bill. The lower end of this range assumes that 50 percent of NJ FamilyCare managed care plans would be required to increase coverage of biomarker testing from current coverage levels. The higher end of this range assumes that 75 percent of the NJ FamilyCare managed care plans would increase biomarker testing coverage under the bill. These utilization rates are based on assumptions in the Milliman analysis previously referenced. State revenues, in the form of federal Medicaid reimbursements for qualifying State Medicaid expenditures, will increase in a range from \$755,000 to \$1.4 million annually. As such, the bill's provisions will have a net fiscal impact on NJ FamilyCare expenditures ranging from \$372,000 to \$670,000 annually.

Currently, the NJ FamilyCare program covers a limited number of biomarker tests for certain enrollees who access health care services on a fee-for-service basis. The extent to which biomarker testing is covered for NJ FamilyCare beneficiaries enrolled in a NJ FamilyCare managed care plan, however, is unclear. The 2024 contract between the NJ FamilyCare managed care plans and the Division of Medical Assistance and Health Services in the Department of Human Services simply requires a managed care plan to "...have policies and procedures in place for how it will provide for genetic testing and counseling." Because the rates that the NJ FamilyCare managed care plans pay for contracted laboratory services are proprietary, and publicly available Medicaid claims data do not provide utilization rates for specific laboratory tests, the OLS cannot determine current NJ FamilyCare expenditures or utilization rates for various biomarker tests.

Section: State Government
Analyst: Anna Harris
Associate Fiscal Analyst
Approved: Thomas Koenig
Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

SENATE, No. 3098

STATE OF NEW JERSEY
221st LEGISLATURE

INTRODUCED APRIL 11, 2024

Sponsored by:

Senator VIN GOPAL

District 11 (Monmouth)

Senator TROY SINGLETON

District 7 (Burlington)

Co-Sponsored by:

**Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan,
McKnight, Beach, Cruz-Perez, Zwicker and Bramnick**

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 10/21/2024)

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

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
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 P.L. , c. (C.) (pending before the
14 Legislature as this bill), shall provide coverage for biomarker
15 testing, as defined by subsection g. of this section.

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

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

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

24 (3) warnings and precautions on FDA-approved drug labels;

25 (4) Centers for Medicare and Medicaid Services National
26 Coverage Determinations or Medicare Administrative Contractor
27 Local Coverage Determinations; or

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

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

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

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

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

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

4 g. As used in this section:

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

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

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

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

31

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

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

- 45 (1) labeled indications for an FDA-approved or -cleared test;
46 (2) indicated tests for an FDA-approved drug;
47 (3) warnings and precautions on FDA-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 and
5 consensus statements.

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 a subscriber.

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

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

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

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

26 g. As used in this section:

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

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

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

45 “Nationally-recognized clinical practice guidelines” means
46 evidence-based clinical practice guidelines developed by
47 independent organizations or medical professional societies
48 utilizing a transparent methodology and reporting structure and with

1 a conflict of interest policy. The guidelines establish standards of
2 care informed by a systematic review of evidence and an
3 assessment of the benefits and risks of alternative care options and
4 include recommendations intended to optimize patient care.

5

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

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

- 19 (1) labeled indications for an FDA-approved or -cleared test;
20 (2) indicated tests for an FDA-approved drug;
21 (3) warnings and precautions on FDA-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 and
26 consensus statements.

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 subscriber.

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

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

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

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

47 g. As used in this section:

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

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

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

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

27

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

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

- 41 (1) labeled indications for an FDA-approved or -cleared test;
- 42 (2) indicated tests for an FDA-approved drug;
- 43 (3) warnings and precautions on FDA-approved drug labels;
- 44 (4) Centers for Medicare and Medicaid Services National
45 Coverage Determinations or Medicare Administrative Contractor
46 Local Coverage Determinations; or
- 47 (5) nationally-recognized clinical practice guidelines and
48 consensus statements.

- 1 c. Coverage, pursuant to subsection b. of this section, shall be
2 provided in a manner that limits disruption, including multiple
3 biopsies or biospecimen samples, in the care of an insured.
- 4 d. (1) Notwithstanding any other law, rule, or regulation to the
5 contrary, if utilization review is required, a decision shall be
6 rendered on a prior authorization request, and notice shall be sent to
7 the insured and the appropriate health care provider, and if the
8 request is made through a health care entity, to the health care
9 entity, within 72 hours for a non-urgent request or 24 hours for an
10 urgent request.
- 11 (2) The insured and the treating health care provider or treating
12 health care entity prescribing biomarker testing for the insured shall
13 have access to clear, readily accessible, and conspicuous
14 information on the process to submit an appeal to an adverse
15 determination.
- 16 e. The benefits shall be provided to the same extent as for any
17 other medical condition under the contract.
- 18 f. The provisions of this section shall apply to all health
19 benefits plans in which the carrier has reserved the right to change
20 the premium.
- 21 g. As used in this section:
- 22 “Biomarker” means a characteristic that is objectively measured
23 and evaluated as an indicator of normal biological processes,
24 pathogenic processes, or pharmacologic responses to a specific
25 therapeutic intervention, including known gene-drug interactions
26 for medications being considered for use or already being
27 administered. Biomarkers shall also include, but not be limited to,
28 gene mutations, characteristics of genes, or protein expression.
- 29 “Biomarker testing” means the analysis of tissue, blood, or other
30 biospecimen for the presence of a biomarker. Biomarker testing
31 includes but is not limited to, single-analyte tests, multiplex panel
32 tests, protein expression, and whole exome, whole genome, and
33 whole transcriptome sequencing.
- 34 “Consensus statement” means a statement developed by an
35 independent, multidisciplinary panel of experts utilizing a
36 transparent methodology and reporting structure and with a conflict
37 of interest policy. The statement shall be aimed at specific clinical
38 circumstances and be based on the best available evidence for the
39 purpose of optimizing the outcomes of clinical care.
- 40 “Nationally-recognized clinical practice guidelines” means
41 evidence-based clinical practice guidelines developed by
42 independent organizations or medical professional societies
43 utilizing a transparent methodology and reporting structure and with
44 a conflict of interest policy. The guidelines establish standards of
45 care informed by a systematic review of evidence and an
46 assessment of the benefits and risks of alternative care options and
47 include recommendations intended to optimize patient care.

1 5. a. Each group health insurance policy that provides hospital
2 or medical expense benefits and is delivered, issued, executed, or
3 renewed in this State pursuant to chapter 27 of Title 17B of the New
4 Jersey Statutes or is approved for issuance or renewal in this State
5 by the Commissioner of Banking and Insurance, on or after the
6 effective date of P.L. , c. (C.) (pending before the
7 Legislature as this bill), shall provide benefits for biomarker testing,
8 as defined by subsection g. of this section.

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

- 14 (1) labeled indications for an FDA-approved or -cleared test;
- 15 (2) indicated tests for an FDA-approved drug;
- 16 (3) warnings and precautions on FDA-approved drug labels;
- 17 (4) Centers for Medicare and Medicaid Services National
18 Coverage Determinations or Medicare Administrative Contractor
19 Local Coverage Determinations; or
- 20 (5) nationally-recognized clinical practice guidelines and
21 consensus statements.

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

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

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

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

39 f. The provisions of this section shall apply to all policies in
40 which the insurer 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
47 administered. Biomarkers shall also include, but not be limited to,
48 gene mutations, characteristics of genes, or protein expression.

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

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

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

20

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

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

- 34 (1) labeled indications for an FDA-approved or -cleared test;
35 (2) indicated tests for an FDA-approved drug;
36 (3) warnings and precautions on FDA-approved drug labels;
37 (4) Centers for Medicare and Medicaid Services National
38 Coverage Determinations or Medicare Administrative Contractor
39 Local Coverage Determinations; or
40 (5) nationally-recognized clinical practice guidelines and
41 consensus statements.

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

45 d. (1) Notwithstanding any other law, rule, or regulation to the
46 contrary, if utilization review is required, a decision shall be
47 rendered on a prior authorization request, and notice shall be sent to
48 the covered person and the appropriate health care provider, and if

1 the 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.

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

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

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

14 g. As used in this section:

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

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

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

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

41

42 7. a. Each small employer health benefits plan that provides
43 hospital or medical expense benefits and is delivered, issued,
44 executed, or renewed in this State pursuant to P.L.1992, c.162
45 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in
46 this State by the Commissioner of Banking and Insurance, on or
47 after the effective date of P.L. , c. (C.) (pending before the

1 Legislature as this bill), shall provide benefits for biomarker testing,
2 as defined by subsection g. of this section.

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

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

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

10 (3) warnings and precautions on FDA-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 and
15 consensus statements.

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 covered person.

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

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

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

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

36 g. As used in this section:

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

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

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

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

15
16 8. a. Each health maintenance organization contract for health
17 care services that is delivered, issued, executed, or renewed in this
18 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved
19 for issuance or renewal in this State by the Commissioner of
20 Banking and Insurance, on or after the effective date of P.L. ,
21 c. (C.) (pending before the Legislature as this bill), shall
22 provide health care services for biomarker testing, as defined by
23 subsection g. of this section.

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

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

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

31 (3) warnings and precautions on FDA-approved drug labels;

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

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

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

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

47 (2) The enrollee and the treating health care provider or treating
48 health care entity prescribing biomarker testing for the enrollee

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

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

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

10 g. As used in this section:

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

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

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

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

37
38 9. a. The State Health Benefits Commission shall ensure that
39 every contract providing hospital or medical expense benefits,
40 which is purchased by the commission on or after the effective date
41 of P.L. , c. (C.) (pending before the Legislature as this
42 bill), provides coverage for biomarker testing, as defined by
43 subsection e. of this section.

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

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

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

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

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

24 e. As used in this section:

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

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

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

43 “Nationally-recognized clinical practice guidelines” means
44 evidence-based clinical practice guidelines developed by
45 independent organizations or medical professional societies
46 utilizing a transparent methodology and reporting structure and with
47 a conflict of interest policy. The guidelines establish standards of
48 care informed by a systematic review of evidence and an

1 assessment of the benefits and risks of alternative care options and
2 include recommendations intended to optimize patient care.

3

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

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

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

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

17 (3) warnings and precautions on FDA-approved drug labels;

18 (4) Centers for Medicare and Medicaid Services National
19 Coverage Determinations or Medicare Administrative Contractor
20 Local Coverage Determinations; or

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

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

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

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

38 e. As used in this section:

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

46 "Biomarker testing" means the analysis of tissue, blood, or other
47 biospecimen for the presence of a biomarker. Biomarker testing
48 includes but is not limited to, single-analyte tests, multiplex panel

1 tests, protein expression, and whole exome, whole genome, and
2 whole transcriptome sequencing.

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

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

17

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

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

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

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

30 (3) warnings and precautions on FDA-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 and
35 consensus statements.

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

46 e. (1) Notwithstanding any other law, rule, or regulation to the
47 contrary, if utilization review is required, a decision shall be
48 rendered on a prior authorization request, and notice be sent to an

1 individual, the appropriate health care provider, and, if necessary,
2 the requisite health care entity if the request for prior authorization
3 was submitted through the entity, within 72 hours for a non-urgent
4 request or 24 hours for an urgent request.

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

10 f. As used in this section:

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

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

23

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

27

28

29

STATEMENT

30

31 This bill requires health insurers to cover biomarker testing.
32 Under the bill, health insurance carriers (including health service
33 corporations, hospital service corporations, medical service
34 corporations, commercial individual and group health insurers,
35 health maintenance organizations, entities contracted to administer
36 health benefits in connection with the State Health Benefits
37 Program and School Employees’ Health Benefits Program, and
38 Medicaid) are to cover testing for the purposes of diagnosis,
39 treatment, appropriate management, or ongoing monitoring of an
40 individual’s disease or condition when the test is supported by
41 medical and scientific evidence. The evidence includes, but is not
42 limited to: (1) labeled indications for an FDA-approved or -cleared
43 test; (2) indicated tests for an FDA-approved drug; (3)
44 warnings and precautions on FDA-approved drug labels; (4)
45 Centers for Medicare and Medicaid Services National Coverage
46 Determinations or Medicare Administrative Contractor Local

S3098 GOPAL, SINGLETON

18

1 Coverage Determinations; or (5) Nationally recognized clinical
2 practice guidelines and consensus statements. Coverage is to be
3 provided in a manner that limits disruption, including multiple
4 biopsies or biospecimen samples, in the care of an individual. The
5 bill also stipulates timelines in which a decision on prior
6 authorization is to be made.

[First Reprint]

SENATE, No. 3098

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED APRIL 11, 2024

Sponsored by:

Senator VIN GOPAL

District 11 (Monmouth)

Senator TROY SINGLETON

District 7 (Burlington)

Co-Sponsored by:

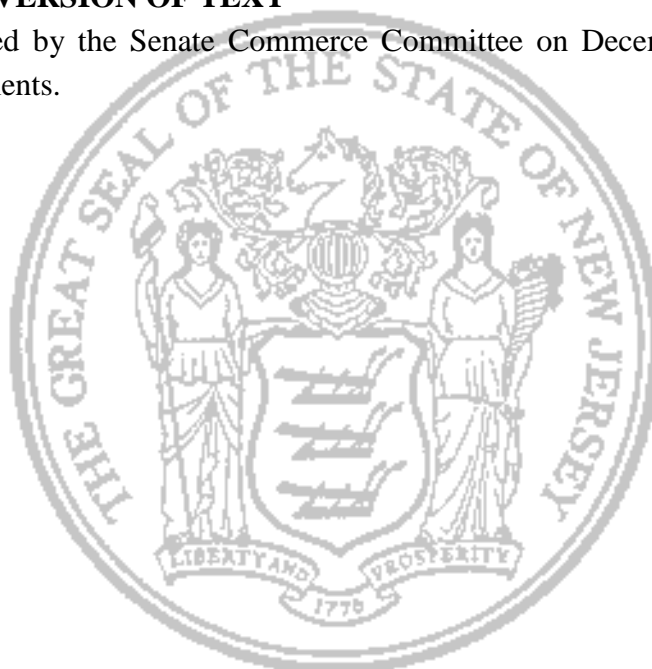
Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan, McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer and Wimberly

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As reported by the Senate Commerce Committee on December 12, 2024, with amendments.



(Sponsorship Updated As Of: 3/17/2025)

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

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
8 1. a. Each hospital service corporation contract that provides
9 hospital or medical expense benefits and is delivered, issued, executed,
10 or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et
11 seq.) or is approved for issuance or renewal in this State by the
12 Commissioner of Banking and Insurance, on or after the effective date
13 of P.L. , c. (C.) (pending before the Legislature as this bill),
14 shall provide coverage for biomarker testing, as defined by subsection
15 g. of this section.

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

- 20 (1) labeled indications for an FDA-approved or FDA-cleared test;
21 (2) indicated tests for an FDA-approved drug;
22 (3) warnings and precautions on FDA-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 and
27 consensus statements.

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

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

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

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:

¹Senate SCM committee amendments adopted December 12, 2024.

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

3 f. The provisions of this section shall apply to all hospital service
4 corporation contracts in which the hospital service corporation has
5 reserved the right to change 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 for
11 medications being considered for use or already being administered.
12 Biomarkers shall also include, but not be limited to, gene mutations,
13 characteristics of genes, or protein expression.

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

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

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

33

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

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

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

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

48 (3) warnings and precautions on FDA-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 and
5 consensus statements.

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

9 d. (1) ¹【Notwithstanding any other law, rule, or regulation to
10 the contrary, if】 If¹ utilization review is required, ¹a medical service
11 corporation shall provide¹ a decision ¹【shall be rendered on a prior
12 authorization request, and notice shall be sent to the subscriber and the
13 appropriate health care provider, and if the request is made through a
14 health care entity, to the health care entity, within 72 hours for a non-
15 urgent request or 24 hours for an urgent request】 pursuant to the
16 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
17 et. al)¹.

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

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

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

27 g. As used in this section:

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

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

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

46 “Nationally-recognized clinical practice guidelines” means
47 evidence-based clinical practice guidelines developed by independent

1 organizations or medical professional societies utilizing a transparent
2 methodology and reporting structure and with a conflict of interest
3 policy. The guidelines establish standards of care informed by a
4 systematic review of evidence and an assessment of the benefits and
5 risks of alternative care options and include recommendations intended
6 to optimize patient care.

7
8 3. a. Each health service corporation contract that provides
9 hospital or medical expense benefits and is delivered, issued, executed,
10 or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et
11 seq.) or is approved for issuance or renewal in this State by the
12 Commissioner of Banking and Insurance, on or after the effective date
13 of P.L. , c. (C.) (pending before the Legislature as this bill),
14 shall provide coverage for biomarker testing, as defined by subsection
15 g. of this section.

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

- 20 (1) labeled indications for an FDA-approved or -cleared test;
21 (2) indicated tests for an FDA-approved drug;
22 (3) warnings and precautions on FDA-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 and
27 consensus statements.

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

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

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

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

1 g. As used in this section:

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

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

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

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

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

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

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

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

43 (3) warnings and precautions on FDA-approved drug labels;

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

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

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

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

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

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

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

21 g. As used in this section:

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

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

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

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

1 5. a. Each group health insurance policy that provides hospital or
2 medical expense benefits and is delivered, issued, executed, or
3 renewed in this State pursuant to chapter 27 of Title 17B of the New
4 Jersey Statutes or is approved for issuance or renewal in this State by
5 the Commissioner of Banking and Insurance, on or after the effective
6 date of P.L. , c. (C.) (pending before the Legislature as this
7 bill), shall provide benefits for biomarker testing, as defined by
8 subsection g. of this section.

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

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

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

15 (3) warnings and precautions on FDA-approved drug labels;

16 (4) Centers for Medicare and Medicaid Services National
17 Coverage Determinations or Medicare Administrative Contractor
18 Local Coverage Determinations; or

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

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

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

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

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

38 f. The provisions of this section shall apply to all policies in
39 which the insurer has reserved the right to change 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 for
45 medications being considered for use or already being administered.
46 Biomarkers shall also include, but not be limited to, gene mutations,
47 characteristics of genes, or protein expression.

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

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

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

20

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

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

- 34 (1) labeled indications for an FDA-approved or -cleared test;
35 (2) indicated tests for an FDA-approved drug;
36 (3) warnings and precautions on FDA-approved drug labels;
37 (4) Centers for Medicare and Medicaid Services National
38 Coverage Determinations or Medicare Administrative Contractor
39 Local Coverage Determinations; or
40 (5) nationally-recognized clinical practice guidelines and
41 consensus statements.

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

45 d. (1) ¹“Notwithstanding any other law, rule, or regulation to
46 the contrary, if” If¹ utilization review is required, ¹a carrier shall
47 provide¹ a decision ¹“shall be rendered on a prior authorization
48 request, and notice shall be sent to the covered person and the

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

6 (2) The covered person and the treating health care provider or
7 treating health care entity prescribing biomarker testing for the
8 covered person 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 health benefits plan.

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

16 g. As used in this section:

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

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

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

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

43
44 7. a. Each small employer health benefits plan that provides
45 hospital or medical expense benefits and is delivered, issued, executed,
46 or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et
47 seq.) or is approved for issuance or renewal in this State by the
48 Commissioner of Banking and Insurance, on or after the effective date

1 of P.L. , c. (C.) (pending before the Legislature as this bill),
2 shall provide benefits for biomarker testing, as defined by subsection
3 g. of this section.

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

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

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

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

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

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

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

39 g. As used in this section:

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

47 “Biomarker testing” means the analysis of tissue, blood, or other
48 biospecimen for the presence of a biomarker. Biomarker testing

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

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

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

18

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

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

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

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

33 (3) warnings and precautions on FDA-approved drug labels;

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

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

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

42 d. (1) ¹["Notwithstanding any other law, rule, or regulation to
43 the contrary, if] If¹ utilization review is required, ¹a health
44 maintenance organization shall provide¹ a decision ¹["shall be rendered
45 on a prior authorization request, and notice shall be sent to the enrollee
46 and the appropriate health care provider, and if the request is made
47 through a health care entity, to the health care entity, within 72 hours

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

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

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

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

14 g. As used in this section:

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

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

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

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

41

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

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

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

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

8 (3) warnings and precautions on FDA-approved drug labels;

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

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

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

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

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

30 e. As used in this section:

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

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

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

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

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

11

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

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

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

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

25 (3) warnings and precautions on FDA-approved drug labels;

26 (4) Centers for Medicare and Medicaid Services National
27 Coverage Determinations or Medicare Administrative Contractor
28 Local Coverage Determinations; or

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

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

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

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

47 e. As used in this section:

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

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

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

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

27

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

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

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

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

39 (3) warnings and precautions on FDA-approved drug labels;

40 (4) Centers for Medicare and Medicaid Services National
41 Coverage Determinations or Medicare Administrative Contractor
42 Local Coverage Determinations; or

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

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

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

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

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

20 f. As used in this section:

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

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

33
34 12. This act shall take effect on the 90th day next following
35 enactment and shall apply to policies and contracts issued or
36 renewed on or after the effective date.

[Second Reprint]

SENATE, No. 3098

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED APRIL 11, 2024

Sponsored by:

Senator VIN GOPAL

District 11 (Monmouth)

Senator TROY SINGLETON

District 7 (Burlington)

Co-Sponsored by:

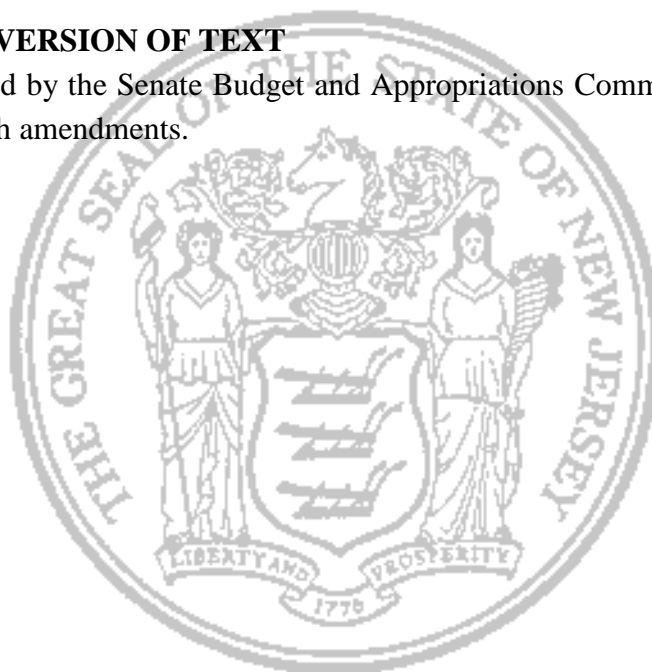
Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan, McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer, Wimberly and O'Scanlon

SYNOPSIS

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

CURRENT VERSION OF TEXT

As reported by the Senate Budget and Appropriations Committee on March 17, 2025, with amendments.



(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.

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
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.
16 of 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 condition ², excluding
20 asymptomatic screening, to guide treatment decisions² of a
21 subscriber when the ²**test is supported by medical and scientific**
22 **evidence, including, but not limited to** efficacy and
23 appropriateness of biomarker precision medical testing for the
24 diagnosis, treatment, appropriate management, or guiding treatment
25 decisions for a 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** If¹ 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:

¹Senate SCM committee amendments adopted December 12, 2024.

²Senate SBA committee amendments adopted March 17, 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
7 medical² 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 contract ², including
12 determinations of clinical review criteria used for utilization review
13 of 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.
9 of 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 condition ², excluding
13 asymptomatic screening, to guide treatment decisions² of a
14 subscriber when the ²[test is supported by medical and scientific
15 evidence, including, but not limited to] efficacy and
16 appropriateness of biomarker precision medical testing for the
17 diagnosis, treatment, appropriate management, or guiding treatment
18 decisions for a 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
42 medical² 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 contract ², including

1 determinations of clinical review criteria used for utilization review
2 of 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.
44 of 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 condition ², excluding

1 asymptomatic screening, to guide treatment decisions² of a
2 subscriber when the ²**[test is supported by medical and scientific**
3 **evidence, including, but not limited to]** efficacy and
4 appropriateness of biomarker precision medical testing for the
5 diagnosis, treatment, appropriate management, or guiding treatment
6 decisions for a 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
30 medical² 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 contract ², including
35 determinations of clinical review criteria used for utilization review
36 of 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 condition ², 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) ²actions 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 contract ², including
25 determinations of clinical review criteria used for utilization review
26 of 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.
21 of 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 contract ², including
13 determinations of clinical review criteria used for utilization review
14 of 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 condition ², 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
15 appropriateness of biomarker precision medical testing for the
16 diagnosis, treatment, appropriate management, or guiding treatment
17 decisions for a covered person's disease or condition is recognized
18 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 covered person.

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

40 (2) The covered person and the treating health care provider or
41 treating health care entity prescribing biomarker ²precision
42 medical² testing for the covered person shall have access to clear,
43 readily accessible, and conspicuous information on the process to
44 submit an 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 health benefits plan², including

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

4 f. The provisions of this section shall apply to all health
5 benefits plans in which the carrier has reserved the right to change
6 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 7. a. Each small employer health benefits plan that provides
37 hospital or medical expense benefits and is delivered, issued,
38 executed, or renewed in this State pursuant to P.L.1992, c.162
39 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in
40 this State by the Commissioner of Banking and Insurance, on or
41 after the effective date of ²【P.L. , c. (C.) (pending before
42 the Legislature as this bill)】 this act², shall provide benefits for
43 biomarker ²precision medical² testing, as defined by subsection g.
44 of 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 condition ², excluding

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

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

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

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

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

34 e. The benefits shall be provided to the same extent as for any
35 other medical condition under the health benefits plan ², including
36 determinations of clinical review criteria used for utilization review
37 of health care services along with copayment, deductible, and
38 coinsurance provisions².

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

42 g. As used in this section:

43 “Biomarker” means a characteristic that is objectively measured
44 and evaluated as an indicator of normal biological processes,
45 pathogenic processes, or pharmacologic responses to a specific
46 therapeutic intervention, including known gene-drug interactions

1 for medications being considered for use or already being
2 administered. Biomarkers shall also include, but not be limited to,
3 gene mutations, characteristics of genes, or protein expression.

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

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

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

24

25 8. a. Each health maintenance organization contract for health
26 care services that is delivered, issued, executed, or renewed in this
27 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved
28 for issuance or renewal in this State by the Commissioner of
29 Banking and Insurance, on or after the effective date of ²【P.L. ,
30 c. (C.) (pending before the Legislature as this bill)】 this act²,
31 shall provide health care services for biomarker ²precision medical²
32 testing, as defined by 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 condition ², excluding
36 asymptomatic screening, to guide treatment decisions² of an
37 enrollee when the ²【test is supported by medical and scientific
38 evidence, including, but not limited to】 efficacy and
39 appropriateness of biomarker precision medical testing for the
40 diagnosis, treatment, appropriate management, or guiding treatment
41 decisions for an enrollee’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) ²actions 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 enrollee.

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

18 (2) The enrollee and the treating health care provider or treating
19 health care entity prescribing biomarker ²precision medical² testing
20 for the enrollee 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 health care services shall be provided to the same extent
24 as for any other medical condition under the contract ², including
25 determinations of clinical review criteria used for utilization review
26 of health care services along with copayment, deductible, and
27 coinsurance provisions².

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

32 g. As used in this section:

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

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

46 ¹“Consensus statement” means a statement developed by an
47 independent, multidisciplinary panel of experts utilizing a

1 transparent methodology and reporting structure and with a conflict
2 of interest policy. The statement shall be aimed at specific clinical
3 circumstances and be based on the best available evidence for the
4 purpose of optimizing the outcomes of clinical care.】¹

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

13

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

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

- 30 (1) labeled indications for an FDA-approved or -cleared test;
31 (2) indicated tests for an FDA-approved drug;
32 (3) ²actions to address² warnings and precautions on FDA-
33 approved drug labels;
34 (4) Centers for Medicare and Medicaid Services National
35 Coverage Determinations or Medicare Administrative Contractor
36 Local Coverage Determinations; or
37 (5) nationally-recognized clinical practice guidelines ²[and
38 consensus statements]².

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

42 d. (1) ¹[Notwithstanding any other law, rule, or regulation
43 to the contrary, if] If¹ utilization review is required, a decision shall
44 be rendered ¹[on a prior authorization request, and notice shall be
45 sent to the covered person and the appropriate health care provider,
46 and if the request is made through a health care entity, to the health
47 care entity, within 72 hours for a non-urgent request or 24 hours for

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

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

8 e. As used in this section:

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

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

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

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

36
37 10. a. The School Employees’ Health Benefits Commission
38 shall ensure that every contract providing hospital or medical
39 expense benefits, which is purchased by the commission on or after
40 the effective date of ²[P.L. , c. (C.) (pending before the
41 Legislature as this bill)] this act², provides coverage for biomarker
42 ²precision medical² testing, as defined by subsection e. of this
43 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 condition ², excluding
47 asymptomatic screening, to guide treatment decisions² of a covered

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

19 d. (1) ¹[Notwithstanding any other law, rule, or regulation
20 to the contrary, if] If¹ utilization review is required, a decision shall
21 be rendered ¹[on a prior authorization request, and notice shall be
22 sent to the covered person and the appropriate health care provider,
23 and if the request is made through a health care entity, to the health
24 care entity, within 72 hours for a non-urgent request or 24 hours for
25 an urgent request] pursuant to the guidelines and timeframes set
26 forth in P.L.2023, c.296 (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
29 medical² testing for the covered person shall have access to clear,
30 readily accessible, and conspicuous information on the process to
31 submit an appeal to an adverse determination.

32 e. As used in this section:

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

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

1 ¹["Consensus statement" means a statement developed by an
2 independent, multidisciplinary panel of experts utilizing a
3 transparent methodology and reporting structure and with a conflict
4 of interest policy. The statement shall be aimed at specific clinical
5 circumstances and be based on the best available evidence for the
6 purpose of optimizing the outcomes of clinical care.]¹

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

15
16 11. a. Notwithstanding any State law or regulation to the
17 contrary, the Department of Human Services shall ensure that
18 expenses incurred for biomarker ²precision medical² testing shall be
19 provided with no cost-sharing to persons served under the Medicaid
20 program, established pursuant to P.L.1968, c.413 (C.30:4D-
21 1 et seq.).

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 condition ², excluding
25 asymptomatic screening, to guide treatment decisions² of an
26 individual when the ²["test is supported by medical and scientific
27 evidence, including, but not limited to"] efficacy and
28 appropriateness of biomarker precision medical testing for the
29 diagnosis, treatment, appropriate management, or guiding treatment
30 decisions for an individual'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 individual.

43 d. If the Division of Medical Assistance and Health Services in
44 the Department of Human Services contracts with a third-party
45 entity to deliver biomarker ²precision medical² testing services
46 pursuant to this section to beneficiaries under the Medicaid
47 program, the third-party entity shall provide biomarker ²precision

1 medical² testing at the same scope, duration and frequency as the
2 Medicaid program otherwise provides to individuals.

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

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

17 f. As used in this section:

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

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

31

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

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 3098

with committee amendments

STATE OF NEW JERSEY

DATED: DECEMBER 12, 2024

The Senate Commerce Committee reports favorably and with committee amendments Senate Bill No. 3098.

As amended, this bill requires health insurers to cover biomarker testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The evidence includes, but is not limited to: (1) labeled indications for an FDA-approved or -cleared test; (2) indicated tests for an FDA-approved drug; (3) warnings and precautions on FDA-approved drug labels; (4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or (5) nationally recognized clinical practice guidelines and consensus statements. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

The bill also stipulates that utilization review decisions concerning coverage provided under the bill are to be made in accordance with guidelines and timeframes already present in current law.

As amended and reported by the committee, Senate Bill No. 3098 is identical to Assembly Bill No. 4163 (1R).

COMMITTEE AMENDMENTS

The committee amended the bill to:

(1) require carriers to provide biomarker testing to covered persons pursuant to guidelines and timeframes set forth in the "Ensuring Transparency in Prior Authorization Act," if utilization review is required;

(2) remove the definition of "consensus statement;" and

(3) make a technical correction.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

[First Reprint]

SENATE, No. 3098

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 17, 2025

The Senate Budget and Appropriations Committee reports favorably and with committee amendments Senate Bill No. 3098 (1R).

As amended and reported, this bill requires health insurers to cover biomarker precision medical testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover biomarker precision medical testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition, excluding asymptomatic screening, to guide treatment decisions of an individual. Biomarker precision medical testing is to be covered only when the efficacy and appropriateness of 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. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

The bill also stipulates that utilization review decisions concerning coverage provided under the bill are to be made in accordance with guidelines and timeframes already present in current law, and that coverage for biomarker precision medical testing is to be provided to the same extent as for any other medical condition, including determinations of clinical review criteria used for utilization review of health care services along with copayment, deductible, and coinsurance provisions.

COMMITTEE AMENDMENTS:

The committee amended the bill to:

(1) require health insurers to provide coverage for biomarker precision medical testing 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 under certain conditions;

(2) clarify the circumstances under which biomarker precision medical testing is required to be covered;

(3) add language requiring certain insurers to provide coverage for biomarker precision medical testing to the same extent as for other medical conditions, including clinical review criteria used for utilization review of health care services and copayment, deductible, and coinsurance provisions; and

(4) make technical changes.

FISCAL IMPACT:

Fiscal information for this bill is currently unavailable.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 3098 STATE OF NEW JERSEY 221st LEGISLATURE

DATED: JANUARY 10, 2025

SUMMARY

- Synopsis:** Requires health insurers to provide coverage for biomarker testing.
- Type of Impact:** Annual expenditure increase to the State and participating local entities.
- Agencies Affected:** Division of Pensions and Benefits in the Department of the Treasury; Department of Banking and Insurance; Department of Human Services; Local Governments; School Districts.

Office of Legislative Services Estimate

Fiscal Impact	<u>Annual</u>
State Expenditure Increase for SHBP-State	Indeterminate
Local Expenditure Increase for SHBP-Local and SEHBP	Indeterminate
State Expenditure Impact for GetCoveredNJ	Indeterminate
Net State Expenditure Increase for NJ FamilyCare	\$372,000 to \$670,000

- The Office of Legislative Services (OLS) estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in an annual indeterminate expenditure impact for GetCoveredNJ, the State-based health insurance marketplace.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual net expenditure increases of \$372,000 to \$670,000 for the NJ FamilyCare program, which encompasses the State Medicaid program and the Children's Health Insurance Program.

BILL DESCRIPTION

This bill requires health insurers, including the State Health Benefits Program, the School Employees' Health Benefits Program, and the State Medicaid program, to provide coverage for biomarker testing. Under the bill, testing includes diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The bill also states that utilization review decisions regarding coverage are to be made in accordance with current statutory guidelines and timeframes.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

If large group self-insured plans in the national commercial market serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from a 2022 landscape analysis prepared by Milliman, a consultancy, suggest that requiring health insurance carriers to provide coverage for biomarker testing would increase annual State expenditures by approximately \$0.5 million and collective annual expenditures of participating local entities by approximately \$0.9 million. If self-insured plans that provide coverage to State and local employees through the Group Insurance Commission in Massachusetts serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from an April 2024 analysis by BerryDunn, a consulting firm, suggest that requiring health insurance carriers to provide coverage for biomarker testing would increase annual State expenditures by approximately \$2.5 million and collective annual expenditures of participating local entities by approximately \$4.1 million.

The OLS is unable to determine the number of additional diagnostic, treatment, management, or monitoring procedures that would be newly eligible for coverage under the State Health Benefits Program or the School Employees' Health Benefits Program under the bill's provisions. Additionally, the OLS does not know the employer/employee cost share arrangements that would determine the State and local cost increases for the expanded number of covered procedures. Furthermore, the OLS does not know the utilization review or prior authorization requirements that would impact the distribution and cost of additional procedures provided to covered persons under current or future health benefits contracts negotiated by the State Health Benefits Program and the School Employees' Health Benefits Program and their insurers.

In the absence of this information, the OLS concludes that the bill's provisions will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker testing will result in an annual indeterminate expenditure impact for Get Covered New Jersey, the

State-based health insurance marketplace. New Jersey Health Plan Savings or State-paid subsidies on health insurance premiums for policies offered through the State Marketplace are available to certain individuals and households who meet certain income requirements. If requiring coverage for biomarker testing increases the payment needed to subsidize healthcare services for this population, State costs will increase. There are no data regarding the current level of testing, nor any predictive data on the prevalence of this testing in the future. Since there are multiple types of testing available, each with a different cost baseline, it is not possible to predict with any certainty how the cost structure for each test may change in the future or predict the proportional share each particular test will have in the overall patient pool in the State.

The OLS concludes that State costs will increase anywhere from \$1.1 million to \$2.0 million annually for the NJ FamilyCare program to cover biomarker testing, when supported by specific medical and scientific evidence, as required under the bill. The lower end of this range assumes that 50 percent of NJ FamilyCare managed care plans would be required to increase coverage of biomarker testing from current coverage levels. The higher end of this range assumes that 75 percent of the NJ FamilyCare managed care plans would increase biomarker testing coverage under the bill. These utilization rates are based on assumptions in the Milliman analysis previously referenced. State revenues, in the form of federal Medicaid reimbursements for qualifying State Medicaid expenditures, will increase in a range from \$755,000 to \$1.4 million annually. As such, the bill's provisions will have a net fiscal impact on NJ FamilyCare expenditures ranging from \$372,000 to \$670,000 annually.

Currently, the NJ FamilyCare program covers a limited number of biomarker tests for certain enrollees who access health care services on a fee-for-service basis. The extent to which biomarker testing is covered for NJ FamilyCare beneficiaries enrolled in a NJ FamilyCare managed care plan, however, is unclear. The 2024 contract between the NJ FamilyCare managed care plans and the Division of Medical Assistance and Health Services in the Department of Human Services simply requires a managed care plan to "...have policies and procedures in place for how it will provide for genetic testing and counseling." Because the rates that the NJ FamilyCare managed care plans pay for contracted laboratory services are proprietary, and publicly available Medicaid claims data do not provide utilization rates for specific laboratory tests, the OLS cannot determine current NJ FamilyCare expenditures or utilization rates for various biomarker tests.

Section: State Government

Analyst: Anna Harris
Associate Fiscal Analyst

Approved: Thomas Koenig
Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

LEGISLATIVE FISCAL ESTIMATE

[Second Reprint]

SENATE, No. 3098

STATE OF NEW JERSEY 221st LEGISLATURE

DATED: MARCH 26, 2025

SUMMARY

- Synopsis:** Requires health insurers to provide coverage for biomarker precision medical testing.
- Type of Impact:** Annual expenditure increase to the State and participating local entities.
- Agencies Affected:** Division of Pensions and Benefits in the Department of the Treasury; Department of Banking and Insurance; Department of Human Services; Local Governments; School Districts.

Office of Legislative Services Estimate

Fiscal Impact	<u>Annual</u>
State Expenditure Increase for SHBP-State	Indeterminate
Local Expenditure Increase for SHBP-Local and SEHBP	Indeterminate
State Expenditure Impact for GetCoveredNJ	Indeterminate
Net State Expenditure Increase for NJ FamilyCare	\$372,000 to \$670,000

- The Office of Legislative Services (OLS) estimates that requiring health insurance carriers to provide coverage for biomarker precision medical testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker precision medical testing will result in an annual indeterminate expenditure impact for GetCoveredNJ, the State-based health insurance marketplace.
- The OLS estimates that requiring health insurance carriers to provide coverage for biomarker precision medical testing will result in annual net expenditure increases of \$372,000 to \$670,000 for the NJ FamilyCare program, which encompasses the State Medicaid program and the Children's Health Insurance Program.

BILL DESCRIPTION

This bill requires health insurers, including the State Health Benefits Program, the School Employees' Health Benefits Program, and the State Medicaid program, to provide coverage for biomarker precision medical testing. Under the bill, testing includes diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition, excluding asymptomatic screening, when testing is supported by federal Food and Drug Administration guidelines, federal Centers for Medicare and Medicaid Services guidelines, or nationally-recognized clinical practice guidelines. The bill also states that utilization review decisions regarding coverage are to be made in accordance with current statutory guidelines and timeframes.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker precision medical testing will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

If large group self-insured plans in the national commercial market serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from a 2022 landscape analysis prepared by Milliman, a consultancy, suggest that requiring health insurance carriers to provide coverage for biomarker precision medical testing would increase annual State expenditures by approximately \$0.5 million and collective annual expenditures of participating local entities by approximately \$0.9 million. If self-insured plans that provide coverage to State and local employees through the Group Insurance Commission in Massachusetts serve as a good proxy for the State Health Benefits Program and the School Employees' Health Benefits Program, findings from an April 2024 analysis by BerryDunn, a consulting firm, suggest that requiring health insurance carriers to provide coverage for biomarker precision medical testing would increase annual State expenditures by approximately \$2.5 million and collective annual expenditures of participating local entities by approximately \$4.1 million.

The OLS is unable to determine the number of additional diagnostic, treatment, management, or monitoring procedures that would be newly eligible for coverage under the State Health Benefits Program or the School Employees' Health Benefits Program under the bill's provisions. Additionally, the OLS does not know the employer/employee cost share arrangements that would determine the State and local cost increases for the expanded number of covered procedures. Furthermore, the OLS does not know the utilization review or prior authorization requirements that would impact the distribution and cost of additional procedures provided to covered persons under current or future health benefits contracts negotiated by the State Health Benefits Program and the School Employees' Health Benefits Program and their insurers.

In the absence of this information, the OLS concludes that the bill's provisions will result in annual indeterminate expenditure increases to the State, to local governments that participate in the State Health Benefits Program, and to school districts that participate in the School Employees' Health Benefits Program.

The OLS estimates that requiring health insurance carriers to provide coverage for biomarker precision medical testing will result in an annual indeterminate expenditure impact for Get Covered New Jersey, the State-based health insurance marketplace. New Jersey Health Plan Savings or State-paid subsidies on health insurance premiums for policies offered through the State Marketplace are available to certain individuals and households who meet certain income requirements. If requiring coverage for biomarker precision medical testing increases the payment needed to subsidize healthcare services for this population, State costs will increase. There are no data regarding the current level of testing, nor any predictive data on the prevalence of this testing in the future. Since there are multiple types of testing available, each with a different cost baseline, it is not possible to predict with any certainty how the cost structure for each test may change in the future or predict the proportional share each particular test will have in the overall patient pool in the State.

The OLS concludes that State costs will increase anywhere from \$1.1 million to \$2.0 million annually for the NJ FamilyCare program to cover biomarker precision medical testing, when supported by federal Food and Drug Administration guidelines, federal Centers for Medicare and Medicaid Services guidelines, or nationally-recognized clinical practice guidelines, as required under the bill. The lower end of this range assumes that 50 percent of NJ FamilyCare managed care plans would be required to increase coverage of biomarker precision medical testing from current coverage levels. The higher end of this range assumes that 75 percent of the NJ FamilyCare managed care plans would increase biomarker precision medical testing coverage under the bill. These utilization rates are based on assumptions in the Milliman analysis previously referenced. State revenues, in the form of federal Medicaid reimbursements for qualifying State Medicaid expenditures, will increase in a range from \$755,000 to \$1.4 million annually. As such, the bill's provisions will have a net fiscal impact on NJ FamilyCare expenditures ranging from \$372,000 to \$670,000 annually.

Currently, the NJ FamilyCare program covers a limited number of biomarker precision medical tests for certain enrollees who access health care services on a fee-for-service basis. The extent to which biomarker precision medical testing is covered for NJ FamilyCare beneficiaries enrolled in a NJ FamilyCare managed care plan, however, is unclear. The 2024 contract between the NJ FamilyCare managed care plans and the Division of Medical Assistance and Health Services in the Department of Human Services simply requires a managed care plan to "...have policies and procedures in place for how it will provide for genetic testing and counseling." Because the rates that the NJ FamilyCare managed care plans pay for contracted laboratory services are proprietary, and publicly available Medicaid claims data do not provide utilization rates for specific laboratory tests, the OLS cannot determine current NJ FamilyCare expenditures or utilization rates for various biomarker tests.

Section: State Government Section & Human Services Section

*Analyst: Anna Harris
Associate Fiscal Analyst*

*Anne Hunt Cappabianca
Senior Fiscal Analyst*

*Approved: Thomas Koenig
Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

Governor Phil Murphy

Governor Murphy Takes Action on Legislation

Posted on - 05/8/2025

TRENTON – Today, Governor Murphy signed the following bills into law:

ACS for ACS for A-1825/SCS for S-3533 (Verrelli/McKnight, Bramnick) - Establishes certain guidelines for SHBP, SEHBP, and Medicaid concerning step therapy protocols

A-2813/S-2688 (Greenwald, Reynolds-Jackson, Speight/McKnight, Gopal) - Enters NJ in Social Work Licensure Compact

ACS for A-3940/SCS for S-1635 (Stanley, Schaer/Zwicker, Pou) - Modifies regulation of mortuary science and establishes oversight of mortuary and embalming science

A-4751/S-3606 (DeAngelo, Quijano, Bagolie/Diegnan, A.M. Bucco) - Permits purchase of service credit in SPRS for period of enrollment in military service academy and in New Jersey State Police Academy, and employment as class two special law enforcement officer

ACS for AJR-211/SCS for SJR-149 (Reynolds-Jackson, Sumter, Carter/Turner, Burgess) - Designates May 18 of each year as Six Triple Eight Day in NJ

Governor Murphy conditionally vetoed the following bills:

A-4535/S-2952 (Hutchison, Verrelli, Atkins/Moriarty, Mukherji) – CONDITIONAL - Concerns State regulation of cooperative sober living residences and boarding houses generally; appropriates \$100,000

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A-4652/S-3507 (Hutchison, Murphy/Moriarty, Wimberly) – CONDITIONAL -Establishes offense of inciting public brawl; upgrades penalty for disorderly conduct in certain circumstances

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Posted on: April 23, 2025

Bill Requiring Health Insurance Coverage for Biomarker Testing Signed into Law

Bill A4163 eliminates barriers to essential diagnostic testing, ensuring equitable access for all patients

(TRENTON) — Bill [A4163](#), which will require health insurance carriers to cover biomarker precision medical testing, was signed into law today. The legislation, sponsored by Assemblywoman [Shavonda E. Sumter](#), Assemblyman [Gary S. Schaer](#), and Assemblywoman [Shama A. Haider](#), will enhance patient care and provide equitable access to this vital health resource.



“Everyone deserves access to high-quality medical care, without being held back by financial barriers,” **said Assemblywoman Sumter (D-Bergen, Passaic)**. “This legislation is transformational. By requiring health insurers to cover biomarker testing, we are not only breaking down long-standing barriers to care but also giving patients access to potentially life-saving information. It empowers individuals to make informed decisions about their health and opens the door to more personalized, effective treatment. I’m proud to see this critical bill signed into law and remain steadfast in my commitment to the advocates who have fought tirelessly for equitable access to this essential testing.”

Biomarker testing analyzes an individual’s biological indicators – such as genes, proteins or other substances – to provide insights into their health status or risk of certain diseases. It is often used to identify certain conditions and determine how a patient may respond to treatments, enabling healthcare providers to create tailored treatments that enhance patient health outcomes, minimizing side effects and improving quality of life.

“It is crucial to expand access to personalized treatment through biomarker testing,” **said Assemblyman Schaer (D-Bergen, Passaic)**. “Often times, access to patient specific treatment is not always available to patients under their insurance plan and Medicaid. By guaranteeing insurance coverage, the passage of A4163 will combat healthcare disparities and ensures that all patients receive the quality care they deserve.”

“When patients are faced with uncertainty about their health, the last thing they should have to worry about is whether their insurance will cover the necessary tests that could lead to a diagnosis,” **said Assemblywoman Haider (D-Bergen)**. “A4163 is about providing people with that peace of mind, ensuring they have access to the biomarker testing, regardless of their financial situation.”

By requiring insurance companies to cover biomarker testing, the legislation aims to eliminate uncertainty around insurance coverage and reduces high out-of-pocket costs – barriers to care that have disproportionately affected older adults, people of color, uninsured individuals, and Medicaid recipients.