

[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:

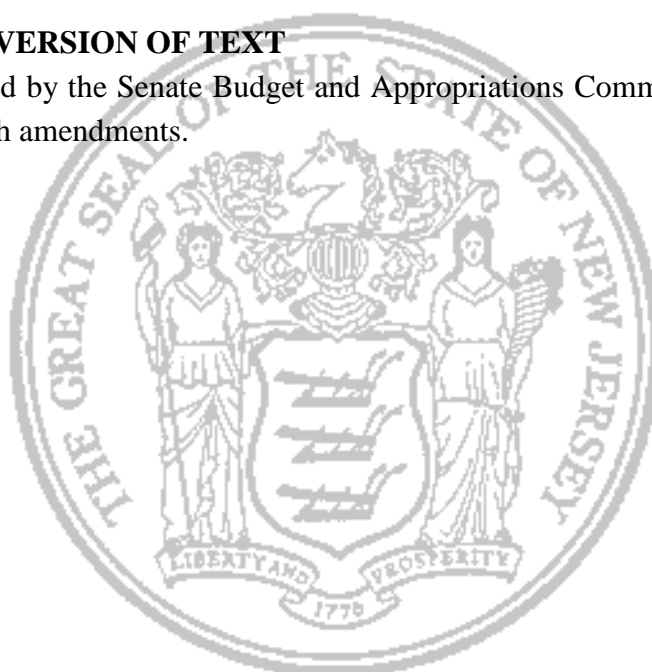
Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan, McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer, Wimberly and O'Scanlon

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 ²test 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 ²and
16 consensus statements².

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