

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:

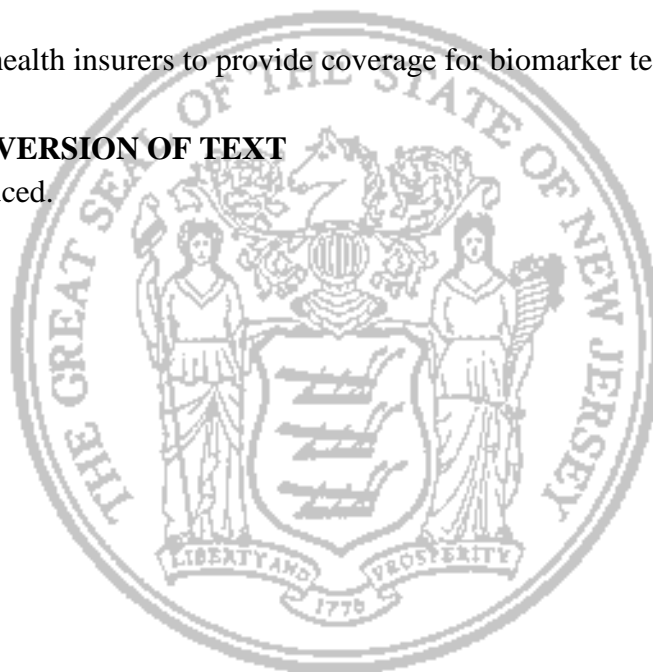
**Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin,
Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn,
Assemblymen Conaway, DePhillips, Calabrese, Barlas, Assemblywoman
Speight, Assemblymen Spearman, DiMaio, Assemblywoman Peterpaul,
Assemblymen McClellan, Simonsen, Hutchison, 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.

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STATEMENT

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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

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- 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.