

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 and Cruz-Perez**

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 6/17/2024)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 g. As used in this section:

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

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

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

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

31

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

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

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

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

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

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

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

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

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

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

26 g. As used in this section:

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

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

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

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

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

5

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

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

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

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

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

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

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

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

47 g. As used in this section:

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

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

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

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

27

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

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

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

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

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

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

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

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

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

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

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

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

41 g. As used in this section:

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

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

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

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

20

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

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

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

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

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

1 the request is made through a health care entity, to the health care
2 entity, within 72 hours for a non-urgent request or 24 hours for an
3 urgent request.

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

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

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

14 g. As used in this section:

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

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

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

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

41

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

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

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

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

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

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

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

14 (5) nationally-recognized clinical practice guidelines and
15 consensus statements.

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

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

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

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

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

36 g. As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 g. As used in this section:

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

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

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

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

37

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

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

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

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

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

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

24 e. As used in this section:

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

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

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

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

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

3

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

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

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

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

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

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

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

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

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

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

38 e. As used in this section:

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

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

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

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

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

17

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

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

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

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

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

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

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

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

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

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

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

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

10 f. As used in this section:

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

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

23

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

27

28

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STATEMENT

30

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

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