

STATE OF NEW YORK

1196--A

2023-2024 Regular Sessions

IN SENATE

January 10, 2023

Introduced by Sens. PERSAUD, ADDABBO, BROUK, CHU, CLEARE, COMRIE, COONEY, GALLIVAN, GIANARIS, GONZALEZ, GOUNARDES, GRIFFO, HARCKHAM, HELMING, HOYLMAN-SIGAL, KENNEDY, KRUEGER, MANNION, MATTERA, MAY, MYRIE, PALUMBO, PARKER, RIVERA, SALAZAR, SCARCELLA-SPANTON, SERRANO, SKOUFIS, STAVISKY, THOMAS, WEIK -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance -- reported favorably from said committee and committed to the Committee on Finance -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the insurance law and the social services law, in relation to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Subsection (i) of section 3216 of the insurance law is
2 amended by adding a new paragraph 11-c to read as follows:

3 (11-c) (A) Every policy which provides medical, major medical, or
4 similar comprehensive-type coverage shall provide coverage for biomarker
5 testing for the purposes of diagnosis, treatment, appropriate manage-
6 ment, or ongoing monitoring of a covered person's disease or condition
7 when the test provides clinical utility to the patient as demonstrated
8 by medical and scientific evidence, including, but not limited to:

9 (i) labeled indications for a test approved or cleared by the federal
10 food and drug administration or indicated tests for a food and drug
11 administration approved drug;

12 (ii) centers for medicare and medicaid services national coverage
13 determinations and medicare administrative contractor local coverage
14 determinations; or

15 (iii) nationally recognized clinical practice guidelines such as, but
16 not limited to, those of the national comprehensive cancer network or
17 the American society of clinical oncology.

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 (B) Such coverage shall be provided in a manner that shall limit
2 disruptions in care including the need for multiple biopsies or biospe-
3 cimen samples.

4 (C) The covered person and prescribing practitioner shall have access
5 to a clear, readily accessible, and convenient process to request an
6 exception to a coverage policy provided pursuant to the provisions of
7 this paragraph. Such process shall be made readily accessible on the
8 website of the insurer.

9 (D) As used in this paragraph, the following terms shall have the
10 following meanings:

11 (i) "Biomarker" means a defined characteristic that is measured as an
12 indicator of normal biological processes, pathogenic processes, or
13 responses to an exposure or intervention, including therapeutic inter-
14 ventions. Molecular, histologic, radiographic, or physiologic character-
15 istics are types of biomarkers. A biomarker is not an assessment of how
16 a patient feels, functions, or survives.

17 (ii) "Biomarker testing" means the analysis of a patient's tissue,
18 blood, or other biospecimen for the presence of a biomarker. Biomarker
19 testing includes but is not limited to single-analyte tests and multi-
20 plex panel tests performed at a participating in-network laboratory
21 facility that is either CLIA certified or CLIA waived by the federal
22 food and drug administration.

23 (iii) "Clinical utility" means the test result provides information
24 that is used in the formulation of a treatment or monitoring strategy
25 that informs a patient's outcome and impacts the clinical decision.

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

33 § 2. Subsection (1) of section 3221 of the insurance law is amended by
34 adding a new paragraph 11-c to read as follows:

35 (11-c) (A) Every insurer delivering a group or blanket policy or issu-
36 ing a group or blanket policy for delivery in this state that provides
37 coverage for medical, major medical, or similar comprehensive-type
38 coverage shall provide coverage for biomarker testing for the purposes
39 of diagnosis, treatment, appropriate management, or ongoing monitoring
40 of a covered person's disease or condition when the test provides clin-
41 ical utility to the patient as demonstrated by medical and scientific
42 evidence, including, but not limited to:

43 (i) labeled indications for a test approved or cleared by the federal
44 food and drug administration or indicated tests for a food and drug
45 administration approved drug;

46 (ii) centers for medicare and medicaid services national coverage
47 determinations and medicare administrative contractor local coverage
48 determinations; or

49 (iii) nationally recognized clinical practice guidelines including,
50 but not limited to, those of the national comprehensive cancer network
51 or the American society of clinical oncology.

52 (B) Such coverage shall be provided in a manner that shall limit
53 disruptions in care including the need for multiple biopsies or biospe-
54 cimen samples.

55 (C) The covered person and prescribing practitioner shall have access
56 to a clear, readily accessible, and convenient process to request an

1 exception to a coverage policy provided pursuant to the provisions of
2 this paragraph. Such process shall be made readily accessible on the
3 website of the insurer.

4 (D) As used in this paragraph, the following terms shall have the
5 following meanings:

6 (i) "Biomarker" means a defined characteristic that is measured as an
7 indicator of normal biological processes, pathogenic processes, or
8 responses to an exposure or intervention, including therapeutic inter-
9 ventions. Molecular, histologic, radiographic, or physiologic character-
10 istics are types of biomarkers. A biomarker is not an assessment of how
11 a patient feels, functions, or survives.

12 (ii) "Biomarker testing" means the analysis of a patient's tissue,
13 blood, or other biospecimen for the presence of a biomarker. Biomarker
14 testing includes but is not limited to single-analyte tests and multi-
15 plex panel tests performed at a participating in-network laboratory
16 facility that is either CLIA certified or CLIA waived by the federal
17 food and drug administration.

18 (iii) "Clinical utility" means the test result provides information
19 that is used in the formulation of a treatment or monitoring strategy
20 that informs a patient's outcome and impacts the clinical decision.

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

28 § 3. Section 4303 of the insurance law is amended by adding a new
29 subsection (p-1) to read as follows:

30 (p-1) (1) A medical expense indemnity corporation, a hospital service
31 corporation or a health service corporation that provides coverage for
32 medical, major medical, or similar comprehensive-type coverage shall
33 provide coverage for biomarker testing for the purposes of diagnosis,
34 treatment, appropriate management, or ongoing monitoring of a covered
35 person's disease or condition when the test provides clinical utility to
36 the patient as demonstrated by medical and scientific evidence, includ-
37 ing, but not limited to:

38 (A) labeled indications for a test approved or cleared by the federal
39 food and drug administration or indicated tests for a food and drug
40 administration approved drug;

41 (B) centers for medicare and medicaid services national coverage
42 determinations and medicare administrative contractor local coverage
43 determinations; or

44 (C) nationally recognized clinical practice guidelines such as, but
45 not limited to, those of the national comprehensive cancer network or
46 the American society of clinical oncology.

47 (2) Such coverage shall be provided in a manner that shall limit
48 disruptions in care including the need for multiple biopsies or biospe-
49 cimen samples.

50 (3) The covered person and prescribing practitioner shall have access
51 to a clear, readily accessible, and convenient process to request an
52 exception to a coverage policy provided pursuant to the provisions of
53 this subsection. Such process shall be made readily accessible on the
54 website of the insurer.

55 (4) As used in this subsection, the following terms shall have the
56 following meanings:

1 (A) "Biomarker" means a defined characteristic that is measured as an
2 indicator of normal biological processes, pathogenic processes, or
3 responses to an exposure or intervention, including therapeutic inter-
4 ventions. Molecular, histologic, radiographic, or physiologic character-
5 istics are types of biomarkers. A biomarker is not an assessment of how
6 a patient feels, functions, or survives.

7 (B) "Biomarker testing" means the analysis of a patient's tissue,
8 blood, or other biospecimen for the presence of a biomarker. Biomarker
9 testing includes but is not limited to single-analyte tests and multi-
10 plex panel tests performed at a participating in-network laboratory
11 facility that is either CLIA certified or CLIA waived by the federal
12 food and drug administration.

13 (C) "Clinical utility" means the test result provides information that
14 is used in the formulation of a treatment or monitoring strategy that
15 informs a patient's outcome and impacts the clinical decision.

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

23 § 4. Subdivision 2 of section 365-a of the social services law is
24 amended by adding a new paragraph (mm) to read as follows:

25 (mm) (i) biomarker testing for the purposes of diagnosis, treatment,
26 appropriate management, or ongoing monitoring of a recipient's disease
27 or condition when the test provides clinical utility to the patient as
28 demonstrated by medical and scientific evidence, including, but not
29 limited to:

30 (1) labeled indications for a test approved or cleared by the federal
31 food and drug administration or indicated tests for a food and drug
32 administration approved drug;

33 (2) centers for medicare and medicaid services national coverage
34 determinations and medicare administrative contractor local coverage
35 determinations; or

36 (3) nationally recognized clinical practice guidelines such as, but
37 not limited to, those of the national comprehensive cancer network or
38 the American society of clinical oncology.

39 (ii) Risk-bearing entities contracted to the medicaid program to
40 deliver services to recipients shall provide biomarker testing at the
41 same scope, duration and frequency as the medicaid program otherwise
42 provides to enrollees.

43 (iii) The recipient and participating provider shall have access to a
44 clear, readily accessible, and convenient process to request an excep-
45 tion to a coverage policy of the medicaid program or by risk-bearing
46 entities contracted to the medicaid program. Such process shall be made
47 readily accessible to all participating providers and enrollees online.

48 (iv) As used in this paragraph, the following terms shall have the
49 following meanings:

50 (1) "Biomarker" means a defined characteristic that is measured as an
51 indicator of normal biological processes, pathogenic processes, or
52 responses to an exposure or intervention, including therapeutic inter-
53 ventions. Molecular, histologic, radiographic, or physiologic character-
54 istics are types of biomarkers. A biomarker is not an assessment of how
55 a patient feels, functions, or survives.

1 (2) "Biomarker testing" means the analysis of a patient's tissue,
2 blood, or other biospecimen for the presence of a biomarker. Biomarker
3 testing includes but is not limited to single-analyte tests and multi-
4 plex panel tests performed at a participating in-network laboratory
5 facility that is either CLIA certified or CLIA waived by the federal
6 food and drug administration.

7 (3) "Clinical utility" means the test result provides information that
8 is used in the formulation of a treatment or monitoring strategy that
9 informs a patient's outcome and impacts the clinical decision.

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

17 § 5. This act shall take effect April 1, 2024 and shall apply to all
18 policies and contracts issued, renewed, modified, altered or amended on
19 or after such date.