

# 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.