

# STATE OF NEW YORK

1673--A

2023-2024 Regular Sessions

## IN ASSEMBLY

January 17, 2023

Introduced by M. of A. HUNTER, DINOWITZ, BRONSON, RAGA, LAVINE, ALVAREZ, McDONALD, PAULIN, GUNTHER, SEAWRIGHT, SEPTIMO, THIELE, SHIMSKY, DE LOS SANTOS, STECK, DAVILA, L. ROSENTHAL, SANTABARBARA, WILLIAMS, BICHOTTE HERMELYN, FAHY, BUTTENSCHON, BURDICK, SIMONE, JACOBSON, BENEDETTO, AUBRY, CRUZ, CLARK, SIMON, ARDILA, ZEBROWSKI, DICKENS, CUNNINGHAM, BURGOS, DURSO, MAHER, BRABENEC, SLATER, MANKTELOW, DeSTEFANO, BARCLAY, EACHUS, MAGNARELLI, NOVAKHOV, LEVENBERG, WEPRIN, MEEKS, ROZIC, PRETLOW, REYES, PHEFFER AMATO, WALKER, KIM, TAYLOR, BURKE, HYNDMAN, RAMOS, WALLACE -- read once and referred to the Committee on Insurance -- reported and referred to the Committee on Ways and Means -- 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

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

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

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

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

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

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

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

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

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

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

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

46 (i) labeled indications for a test approved or cleared by the federal  
47 food and drug administration or indicated tests for a food and drug  
48 administration approved drug;

49 (ii) centers for medicare and medicaid services national coverage  
50 determinations and medicare administrative contractor local coverage  
51 determinations; or

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

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

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

43 (A) 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 (B) centers for medicare and medicaid services national coverage  
47 determinations and medicare administrative contractor local coverage  
48 determinations; or

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

52 (2) 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 (3) 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 subsection. Such process shall be made readily accessible on the  
3 website of the insurer.

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

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

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

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

35 (1) labeled indications for a test approved or cleared by the federal  
36 food and drug administration or indicated tests for a food and drug  
37 administration approved drug;

38 (2) centers for medicare and medicaid services national coverage  
39 determinations and medicare administrative contractor local coverage  
40 determinations; or

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

44 (ii) Risk-bearing entities contracted to the medicaid program to  
45 deliver services to recipients shall provide biomarker testing at the  
46 same scope, duration and frequency as the medicaid program otherwise  
47 provides to enrollees.

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

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

55 (1) "Biomarker" means a defined characteristic that is measured as an  
56 indicator of normal biological processes, pathogenic processes, or

1 responses to an exposure or intervention, including therapeutic inter-  
2 ventions. Molecular, histologic, radiographic, or physiologic character-  
3 istics are types of biomarkers. A biomarker is not an assessment of how  
4 a patient feels, functions, or survives.

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

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

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

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