

# STATE OF NEW YORK

1196

2023-2024 Regular Sessions

## IN SENATE

January 10, 2023

Introduced by Sens. PERSAUD, BROUK, CLEARE, GOUNARDES, HOYLMAN-SIGAL, MANNION, MAY, MYRIE, THOMAS -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance

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:

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

(11-c) (A) Every policy which provides medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(i) labeled indications for a test approved or cleared by the food and drug administration of the United States government or indicated tests for a food and drug administration approved drug;

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

(iii) nationally recognized clinical practice guidelines and consensus statements.

(B) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(C) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of

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

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1 this paragraph. Such process shall be made readily accessible on the  
2 website of the insurer.

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

5 (i) "Biomarker" means a characteristic that is objectively measured  
6 and evaluated as an indicator of normal biological processes, pathogenic  
7 processes, or pharmacologic responses to a specific therapeutic inter-  
8 vention. Biomarkers include but are not limited to gene mutations or  
9 protein expression.

10 (ii) "Biomarker testing" means the analysis of a patient's tissue,  
11 blood, or other biospecimen for the presence of a biomarker. Biomarker  
12 testing includes but is not limited to single-analyte tests, multi-plex  
13 panel tests, and whole genome sequencing.

14 (iii) "Consensus statements" means statements developed by an inde-  
15 pendent, multidisciplinary panel of experts utilizing a transparent  
16 methodology and reporting structure and with a conflict of interest  
17 policy. Such statements are aimed at specific clinical circumstances and  
18 base the statements on the best available evidence for the purpose of  
19 optimizing the outcomes of clinical care.

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

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

30 (11-c) (A) Every insurer delivering a group or blanket policy or issu-  
31 ing a group or blanket policy for delivery in this state that provides  
32 coverage for medical, major medical, or similar comprehensive-type  
33 coverage shall provide coverage for biomarker testing for the purposes  
34 of diagnosis, treatment, appropriate management, or ongoing monitoring  
35 of a covered person's disease or condition when the test is supported by  
36 medical and scientific evidence, including, but not limited to:

37 (i) labeled indications for a test approved or cleared by the food and  
38 drug administration of the United States government or indicated tests  
39 for a food and drug administration approved drug;

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

43 (iii) nationally recognized clinical practice guidelines and consensus  
44 statements.

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

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

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

55 (i) "Biomarker" means a characteristic that is objectively measured  
56 and evaluated as an indicator of normal biological processes, pathogenic

1 processes, or pharmacologic responses to a specific therapeutic inter-  
2 vention. Biomarkers include but are not limited to gene mutations or  
3 protein expression.

4 (ii) "Biomarker testing" means the analysis of a patient's tissue,  
5 blood, or other biospecimen for the presence of a biomarker. Biomarker  
6 testing includes but is not limited to single-analyte tests, multi-plex  
7 panel tests, and whole genome sequencing.

8 (iii) "Consensus statements" means statements developed by an inde-  
9 pendent, multidisciplinary panel of experts utilizing a transparent  
10 methodology and reporting structure and with a conflict of interest  
11 policy. Such statements are aimed at specific clinical circumstances and  
12 base the statements on the best available evidence for the purpose of  
13 optimizing the outcomes of clinical care.

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

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

24 (p-1) (1) A medical expense indemnity corporation, a hospital service  
25 corporation or a health service corporation that provides coverage for  
26 medical, major medical, or similar comprehensive-type coverage shall  
27 provide coverage for biomarker testing for the purposes of diagnosis,  
28 treatment, appropriate management, or ongoing monitoring of a covered  
29 person's disease or condition when the test is supported by medical and  
30 scientific evidence, including, but not limited to:

31 (A) labeled indications for a test approved or cleared by the food and  
32 drug administration of the United States government or indicated tests  
33 for a food and drug administration approved drug;

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

37 (C) nationally recognized clinical practice guidelines and consensus  
38 statements.

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

42 (3) The covered person and prescribing practitioner shall have access  
43 to a clear, readily accessible, and convenient process to request an  
44 exception to a coverage policy provided pursuant to the provisions of  
45 this subsection. Such process shall be made readily accessible on the  
46 website of the insurer.

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

49 (A) "Biomarker" means a characteristic that is objectively measured  
50 and evaluated as an indicator of normal biological processes, pathogenic  
51 processes, or pharmacologic responses to a specific therapeutic inter-  
52 vention. Biomarkers include but are not limited to gene mutations or  
53 protein expression.

54 (B) "Biomarker testing" means the analysis of a patient's tissue,  
55 blood, or other biospecimen for the presence of a biomarker. Biomarker

1 testing includes but is not limited to single-analyte tests, multi-plex  
2 panel tests, and whole genome sequencing.

3 (C) "Consensus statements" means statements developed by an independ-  
4 ent, multidisciplinary panel of experts utilizing a transparent method-  
5 ology and reporting structure and with a conflict of interest policy.  
6 Such statements are aimed at specific clinical circumstances and base  
7 the statements on the best available evidence for the purpose of opti-  
8 mizing the outcomes of clinical care.

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

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

19 (kk) (i) biomarker testing for the purposes of diagnosis, treatment,  
20 appropriate management, or ongoing monitoring of a recipient's disease  
21 or condition when the test is supported by medical and scientific  
22 evidence, including, but not limited to:

23 (1) labeled indications for a test approved or cleared by the food and  
24 drug administration of the United States government or indicated tests  
25 for a food and drug administration approved drug;

26 (2) centers for medicare and medicaid services national coverage  
27 determinations and medicare administrative contractor local coverage  
28 determinations; or

29 (3) nationally recognized clinical practice guidelines and consensus  
30 statements.

31 (ii) Risk-bearing entities contracted to the medicaid program to  
32 deliver services to recipients shall provide biomarker testing at the  
33 same scope, duration and frequency as the medicaid program otherwise  
34 provides to enrollees.

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

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

42 (1) "Biomarker" means a characteristic that is objectively measured  
43 and evaluated as an indicator of normal biological processes, pathogenic  
44 processes, or pharmacologic responses to a specific therapeutic inter-  
45 vention. Biomarkers include but are not limited to gene mutations or  
46 protein expression.

47 (2) "Biomarker testing" means the analysis of a patient's tissue,  
48 blood, or other biospecimen for the presence of a biomarker. Biomarker  
49 testing includes but is not limited to single-analyte tests, multi-plex  
50 panel tests, and whole genome sequencing.

51 (3) "Consensus statements" means statements developed by an independ-  
52 ent, multidisciplinary panel of experts utilizing a transparent method-  
53 ology and reporting structure and with a conflict of interest policy.  
54 Such statements are aimed at specific clinical circumstances and base  
55 the statements on the best available evidence for the purpose of opti-  
56 mizing the outcomes of clinical care.

1     (4) "Nationally recognized clinical practice guidelines" means  
2 evidence-based clinical practice guidelines developed by independent  
3 organizations or medical professional societies utilizing a transparent  
4 methodology and reporting structure and with a conflict of interest  
5 policy. Clinical practice guidelines establish standards of care  
6 informed by a systematic review of evidence and an assessment of the  
7 benefits and costs of alternative care options and include recommenda-  
8 tions intended to optimize patient care.

9     § 5. This act shall take effect January 1, 2024 and shall apply to all  
10 policies and contracts issued, renewed, modified, altered or amended on  
11 or after such date.