

# STATE OF NEW YORK

1673

2023-2024 Regular Sessions

## IN ASSEMBLY

January 17, 2023

Introduced by M. of A. HUNTER, DINOWITZ, BRONSON -- read once and referred 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:

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 is supported by medical and scientific evidence, includ-  
8 ing, but not limited to:

9 (i) labeled indications for a test approved or cleared by the food and  
10 drug administration of the United States government or indicated tests  
11 for a food and drug 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 and consensus  
16 statements.

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

20 (C) The covered person and prescribing practitioner shall have access  
21 to a clear, readily accessible, and convenient process to request an  
22 exception to a coverage policy provided pursuant to the provisions of  
23 this paragraph. Such process shall be made readily accessible on the  
24 website of the insurer.

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

LBD02625-01-3

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

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

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

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

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

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

28 (11-c) (A) Every insurer delivering a group or blanket policy or issu-  
29 ing a group or blanket policy for delivery in this state that provides  
30 coverage for medical, major medical, or similar comprehensive-type  
31 coverage shall provide coverage for biomarker testing for the purposes  
32 of diagnosis, treatment, appropriate management, or ongoing monitoring  
33 of a covered person's disease or condition when the test is supported by  
34 medical and scientific evidence, including, but not limited to:

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

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

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

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

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

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

53 (i) "Biomarker" means a characteristic that is objectively measured  
54 and evaluated as an indicator of normal biological processes, pathogenic  
55 processes, or pharmacologic responses to a specific therapeutic inter-

1 vention. Biomarkers include but are not limited to gene mutations or  
2 protein expression.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 (3) nationally recognized clinical practice guidelines and consensus  
28 statements.

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

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

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

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

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

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

55 (4) "Nationally recognized clinical practice guidelines" means  
56 evidence-based clinical practice guidelines developed by independent

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

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