

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.

(C) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

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

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

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

(1) 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;

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

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

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

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

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

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

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

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Such statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

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

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

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