STATE OF NEW YORK

8502

IN ASSEMBLY

January 4, 2024

Introduced by M. of A. HUNTER -- 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 precision medical testing for certain purposes; and to amend a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, in relation to the effectiveness thereof

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Paragraph 11-c of subsection (i) of section 3216 of the insurance law, as added by a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, is amended to read as follows:

(11-c) (A) Every policy which provides medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker **precision medical** testing for the purposes of diagnosis, treatment, **or** appropriate management **of**, or ongoing monitoring [~~**of a covered person's**~~] **to guide treatment decisions for, an insured's** disease or condition when [~~**the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to**~~] **one or more of the following recognizes the efficacy and appropriateness of biomarker precision medical testing for diagnosis, treatment, appropriate management, or guiding treatment decisions for an insured's disease or condition**:

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

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

LBD02625-08-4

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

(iii) nationally recognized clinical practice guidelines [~~such as, but not limited to, those of the national comprehensive cancer network or the American society of clinical oncology.~~]; or

(iv) peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(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 this paragraph. Such process shall be made readily accessible on the website of the insurer.~~

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

(i) "Biomarker" means a [~~defined~~] characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. [~~Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.~~]

(ii) "Biomarker precision medical 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 and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration.

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

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

§ 2. Paragraph 11-c of subsection (l) of section 3221 of the insurance law, as added by a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, is amended to read as follows:

(11-c) (A) Every insurer delivering a group or blanket policy or issuing a group or blanket policy for delivery in this state that provides coverage for medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker precision medical testing for the purposes of diagnosis, treatment, or appropriate management of, or ongoing monitoring [~~of a covered person's~~] to guide treatment decisions for, an insured's disease or condition when [~~the test provides~~

~~clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to~~] one or more of the following recognizes the efficacy and appropriateness of biomarker precision medical testing for diagnosis, treatment, appropriate management, or guiding treatment decisions for an insured's disease or condition:

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

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

(iii) nationally recognized clinical practice guidelines [~~including, but not limited to, those of the national comprehensive cancer network or the American society of clinical oncology.~~]; or

(iv) peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(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 this paragraph. Such process shall be made readily accessible on the website of the insurer.~~

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

(i) "Biomarker" means a [~~defined~~] characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. [~~Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.~~]

(ii) "Biomarker precision medical 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 and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration.

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

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

§ 3. Subsection (p-1) of section 4303 of the insurance law, as added by a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in

legislative bills numbers S. 1196-A and A. 1673-A, is amended to read as follows:

(p-1) (1) A medical expense indemnity corporation, a hospital service corporation or a health service corporation that provides coverage for medical, major medical, or similar comprehensive-type coverage shall provide coverage for biomarker **precision medical** testing for the purposes of diagnosis, treatment, **or** appropriate management **of**, or ongoing monitoring [~~of a covered person's~~] **to guide treatment decisions for, an insured's** disease or condition when [~~the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to~~] **one or more of the following recognizes the efficacy and appropriateness of biomarker precision medical testing for diagnosis, treatment, appropriate management, or guiding treatment decisions for an insured's disease or condition**:

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

(B) centers for medicare and medicaid services national coverage determinations [~~and~~] **or** medicare administrative contractor local coverage determinations; [~~or~~]

(C) nationally recognized clinical practice guidelines [~~such as, but not limited to, those of the national comprehensive cancer network or the American society of clinical oncology.~~]**; or**

(D) peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

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

(3) [~~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 this subsection. Such process shall be made readily accessible on the website of the insurer.~~

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

(A) "Biomarker" means a [~~defined~~] characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. [~~Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.~~]

(B) "Biomarker **precision medical** 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 and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration.

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

~~(D)~~] "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines informed by a systematic review of evidence and an assessment of the benefits, and risks of

alternative care options intended to optimize patient care developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy.

§ 4. Paragraph (mm) of subdivision 2 of section 365-a of the social services law, as added by a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, is amended to read as follows:

(mm) (i) biomarker **precision medical** testing for the purposes of diagnosis, treatment, **or** appropriate management **of**, or ongoing monitoring [~~of~~] **to guide treatment decisions for,** a recipient's disease or condition when [~~the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to~~] **one or more of the following recognizes the efficacy and appropriateness of biomarker precision medical testing for diagnosis, treatment, appropriate management, or guiding treatment decisions for a recipient's disease or condition**:

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

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

(3) nationally recognized clinical practice guidelines [~~such as, but not limited to, those of the national comprehensive cancer network or the American society of clinical oncology.~~]**; or**

(4) peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(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 [~~defined~~] characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. [~~Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.~~]

(2) "Biomarker **precision medical** 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 and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration.

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

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

§ 5. Section 5 of a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, is amended to read as follows:

§ 5. This act shall take effect [~~April 1, 2024~~] **January 1, 2025** and shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date.

§ 6. This act shall take effect immediately; provided however that sections one, two, three and four of this act shall take effect on the same date and in the same manner as a chapter of the laws of 2023 amending the insurance law and the social services law relating to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes, as proposed in legislative bills numbers S. 1196-A and A. 1673-A, takes effect.