STATE OF NEW YORK

9149

IN ASSEMBLY

January 31, 2022

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 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-b to read as follows:

(11-b) (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 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:

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

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(i) "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.

(ii) "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.

(iii) "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.

(iv) "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.

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

(11-b) (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 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 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 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.

(ii) "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.

(iii) "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.

(iv) "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.

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

(A) 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;

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

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

(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 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.

(B) "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.

(C) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent method-

ology 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 (jj) to read as follows:

(jj) (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, 2023 and shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date.