STATE OF NEW YORK

1673--A

2023-2024 Regular Sessions

IN ASSEMBLY

January 17, 2023

Introduced by M. of A. HUNTER, DINOWITZ, BRONSON, RAGA, LAVINE, ALVAREZ, McDONALD, PAULIN, GUNTHER, SEAWRIGHT, SEPTIMO, THIELE, SHIMSKY, DE LOS SANTOS, STECK, DAVILA, L. ROSENTHAL, SANTABARBARA, WILLIAMS, BICHOTTE HERMELYN, FAHY, BUTTENSCHON, BURDICK, SIMONE, JACOBSON, BENEDETTO, AUBRY, CRUZ, CLARK, SIMON, ARDILA, ZEBROWSKI, DICKENS, CUNNINGHAM, BURGOS, DURSO, MAHER, BRABENEC, SLATER, MANKTELOW, DeSTEFANO, BARCLAY, EACHUS, MAGNARELLI, NOVAKHOV, LEVENBERG, WEPRIN, MEEKS, ROZIC, PRETLOW, REYES, PHEFFER AMATO, WALKER, KIM, TAYLOR, BURKE, HYNDMAN, RAMOS, WALLACE -- read once and referred to the Committee on Insurance -- reported and referred to the Committee on Ways and Means -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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 provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

(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 medicare administrative contractor local coverage determinations; or

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

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(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.

(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 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 multiplex 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. Subsection (l) of section 3221 of the insurance law is amended by adding a new paragraph 11-c 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 testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person'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:

(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 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.

(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 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 multiplex 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. 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 provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

(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 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.

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

(mm) (i) biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of 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:

(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 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.

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