As Introduced

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H. B. No. 24

Representative White

Cosponsors: Representatives Lipps, Manchester, Plummer, Young, T., Liston, Kick, Stewart, Troy, Brennan, Schmidt, Somani, Richardson

A BILL

To enact sections 3902.63 and 5164.13 of the Revised Code to require health benefit plan and Medicaid program coverage of biomarker testing.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3902.63 and 5164.13 of the Revised Code be enacted to read as follows:

Sec. 3902.63. (A) As used in this section, "biomarker," "biomarker testing," "consensus statements," and "nationally recognized clinical practice guidelines" all have the same meanings as in section 5164.13 of the Revised Code.

(B) On and after the effective date of this section, and notwithstanding section 3901.71 of the Revised Code, a health benefit plan issued, renewed, or modified in this state shall cover biomarker testing, subject to division (C) of this section, for any of the following purposes:

(1) Diagnosis;

(2) Treatment and appropriate management of a disease or

condition;

(3) Ongoing monitoring of a disease or condition.

(C) A health benefit plan shall cover biomarker testing for the purposes included in division (B) of this section when the test is supported by medical and scientific evidence, including but not limited to any of the following:

(1) Labeled indications for a United States food and drug administration approved or cleared test;

(2) Indicated tests for a drug approved by the United States food and drug administration;

(3) Warnings and precautions for United States food and drug administration approved drug labels;

(4) National coverage determinations made by the United States centers for medicare and medicaid services;

(5) Medicare administrative contractor local coverage determinations;

(6) Nationally recognized clinical practice guidelines;

(7) Consensus statements.

(D) A health plan issuer shall ensure coverage as required in division (B) of this section in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(E) Any appeal of a biomarker testing coverage determination shall be handled in accordance with the health plan issuer's appeal policy and any other relevant provision of law, including section 1751.82 or Chapter 3922. of the Revised Code. The appeal process shall be made readily accessible to all

participating providers and recipients in writing and online.

Sec. 5164.13. (A) As used in this section:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to specific therapeutic intervention, including known gene-drug interactions for drugs being considered for use or already available for use. Biomarkers include, but are not limited to, gene mutations, characteristics of genes, or protein expression.

(2) "Biomarker testing" means the analysis of tissue, blood, or another biospecimen for the presence of a biomarker, and includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Consensus statements" are statements based on the best available evidence in specific clinical circumstances, are developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy, and are intended to optimize clinical care outcomes.

(4) "Nationally recognized clinical practice guidelines" are evidence-based clinical practice guidelines establishing standards of care informed by a systematic review and assessment of benefits and risks of alternative care options and include recommendations 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.

(B) The medicaid program shall cover biomarker testing,

subject to division (C) of this section, for any of the following purposes:

(1) Diagnosis;

(2) Treatment and appropriate management of a disease or condition;

(3) Ongoing monitoring of a disease or condition.

(C) The medicaid program shall cover biomarker testing for the purposes included in division (B) of this section when the test is supported by medical and scientific evidence, including but not limited to any of the following:

(1) Labeled indications for a United States food and drug administration approved or cleared test;

(2) Indicated tests for a drug approved by the United States food and drug administration;

(3) Warnings and precautions for United States food and drug administration approved drug labels;

(4) National coverage determinations made by the United States centers for medicare and medicaid services;

(5) Medicare administrative contractor local coverage determinations;

(6) Nationally recognized clinical practice guidelines;

(7) Consensus statements.

(D) The Medicaid program shall ensure coverage as required in division (B) of this section in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(E) Any appeal of a biomarker testing coverage policy shall be handled in accordance with section 5160.31 of the Revised Code. The appeal process shall be made readily accessible to all participating providers and recipients in writing and online.