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Representative White

Cosponsors: Representatives Lipps, Manchester, Plummer, Young, T., Liston, Kick, Stewart, Troy, Brennan, Schmidt, Somani, Richardson, Dobos, Lorenz, Abdullahi, Abrams, Baker, Blackshear, Brent, Brewer, Brown, Carruthers, Dell'Aquila, Forhan, Grim, Manning, Miller, A., Mohamed, Patton, Piccolantonio, Robinson, Russo, Sims, Sweeney, Thomas, C., Upchurch, Whitted

A BILL

To enact sections 3902.64 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 3902.64 and 5164.13 of the
Revised Code be enacted to read as follows:

Sec. 3902.64. (A) As used in this section, "biomarker,"
"biomarker testing," and "nationally recognized clinical
practice guidelines" have the same meanings as in section
5164.13 of the Revised Code.

(B) Notwithstanding section 3901.71 of the Revised Code, a
health benefit plan issued, renewed, or modified in this state
on or after the effective date of this section shall cover
biomarker testing for any of the following purposes:

(1) Diagnosis;

<u>(2) Treatment and appropriate management of a disease or</u>	15
<u>condition;</u>	16
<u>(3) Ongoing monitoring of a disease or condition.</u>	17
<u>(C) A health benefit plan shall cover biomarker testing</u>	18
<u>ordered and deemed medically necessary by the qualified treating</u>	19
<u>health care provider working within the provider's scope of</u>	20
<u>practice for the purposes included in division (B) of this</u>	21
<u>section when the test is supported by medical or scientific</u>	22
<u>evidence, as defined by section 3922.01 of the Revised Code,</u>	23
<u>including at least one of the following:</u>	24
<u>(1) Labeled indications for a United States food and drug</u>	25
<u>administration approved or cleared test;</u>	26
<u>(2) Indicated tests for a drug approved by the United</u>	27
<u>States food and drug administration;</u>	28
<u>(3) Warnings and precautions for United States food and</u>	29
<u>drug administration approved drug labels;</u>	30
<u>(4) National coverage determinations made by the United</u>	31
<u>States centers for medicare and medicaid services;</u>	32
<u>(5) Medicare administrative contractor local coverage</u>	33
<u>determinations;</u>	34
<u>(6) Nationally recognized clinical practice guidelines;</u>	35
<u>(7) Nationally recognized and peer reviewed studies</u>	36
<u>indicating that the test materially improves health outcomes.</u>	37
<u>(D) A health plan issuer shall ensure coverage as required</u>	38
<u>in division (B) of this section in a manner that limits</u>	39
<u>disruptions in care, including the need for multiple biopsies or</u>	40
<u>biospecimen samples.</u>	41

(E) Any appeal of a biomarker testing coverage 42
determination shall be handled in accordance with the health 43
plan issuer's appeal policy and any other relevant provision of 44
law, including section 1751.82 or Chapter 3922. of the Revised 45
Code. The appeal process shall be made readily accessible to all 46
participating providers and recipients in writing and online. 47

(F) Nothing in this section shall be construed to require 48
coverage of biomarker testing for screening purposes. 49

Sec. 5164.13. (A) As used in this section: 50

(1) "Biomarker" means a characteristic that is objectively 51
measured and evaluated as an indicator of normal biological 52
processes, pathogenic processes, or pharmacologic responses to 53
specific therapeutic intervention, including known gene-drug 54
interactions for drugs being considered for use or already 55
available for use. Biomarkers include, but are not limited to, 56
gene mutations, characteristics of genes, or protein expression. 57

(2) "Biomarker testing" means the analysis of tissue, 58
blood, or another biospecimen for the presence of a biomarker, 59
and includes, but is not limited to, single-analyte tests, 60
multiplex panel tests, protein expression, and whole exome, 61
whole genome, and whole transcriptome sequencing. 62

(3) "Nationally recognized clinical practice guidelines" 63
are evidence-based clinical practice guidelines establishing 64
standards of care informed by a systematic review and assessment 65
of benefits and risks of alternative care options and include 66
recommendations intended to optimize patient care, developed by 67
independent organizations or medical professional societies 68
utilizing a transparent methodology and reporting structure and 69
with a conflict of interest policy. 70

(B) The medicaid program shall cover biomarker testing, 71
subject to division (C) of this section, for any of the 72
following purposes: 73

(1) Diagnosis; 74

(2) Treatment and appropriate management of a disease or 75
condition; 76

(3) Ongoing monitoring of a disease or condition. 77

(C) The medicaid program shall cover biomarker testing 78
ordered and deemed medically necessary by the qualified treating 79
health care provider working within the provider's scope of 80
practice for the purposes included in division (B) of this 81
section when the test is supported by medical or scientific 82
evidence, as defined by section 3922.01 of the Revised Code, 83
including at least one of the following: 84

(1) Labeled indications for a United States food and drug 85
administration approved or cleared test; 86

(2) Indicated tests for a drug approved by the United 87
States food and drug administration; 88

(3) Warnings and precautions for United States food and 89
drug administration approved drug labels; 90

(4) National coverage determinations made by the United 91
States centers for medicare and medicaid services; 92

(5) Medicare administrative contractor local coverage 93
determinations; 94

(6) Nationally recognized clinical practice guidelines; 95

(7) Nationally recognized and peer reviewed studies 96
indicating that the test materially improves health outcomes. 97

(D) The Medicaid program shall ensure coverage as required 98
in division (B) of this section in a manner that limits 99
disruptions in care, including the need for multiple biopsies or 100
biospecimen samples. 101

(E) Any appeal of a biomarker testing coverage policy 102
shall be handled in accordance with section 5160.31 of the 103
Revised Code. The appeal process shall be made readily 104
accessible to all participating providers and recipients in 105
writing and online. 106

(F) Nothing in this section shall be construed to require 107
coverage of biomarker testing for screening purposes. 108

Section 2. It is the intent of the General Assembly to 109
ensure coverage for appropriate biomarker testing supported by 110
medical or scientific evidence, as defined by section 3922.01 of 111
the Revised Code, with the goal of producing long-term 112
healthcare cost savings and improving health outcomes for 113
Ohioans covered under this act. The General Assembly does not 114
intend to create a landscape which allows manufacturers and 115
administrators of biomarker tests to substantially increase 116
pricing for existing and new biomarker tests as a result of the 117
coverage requirements for certain health insurance markets under 118
this act. 119