As Reported by the House Insurance Committee

134th General Assembly

Regular Session 2021-2022

H. B. No. 608

Representatives White, West

Cosponsors: Representatives Creech, Cross, Koehler, Lanese, Lepore-Hagan, Manchester, Schmidt, Sheehy, Young, T.

A BILL

To enact sections 3902.62 and 5164.13 of the	1
Revised Code to require health benefit plan and	2
Medicaid program coverage of biomarker testing.	3

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

Section 1. That sections 3902.62 and 5164.13 of the	4
Revised Code be enacted to read as follows:	5
Sec. 3902.62. (A) As used in this section, "biomarker,"	6
"biomarker testing," "consensus statements," and "nationally	7
recognized clinical practice guidelines" all have the same	8
meanings as in section 5164.13 of the Revised Code.	9
	1.0
(B) On and after the effective date of this section, and	10
notwithstanding section 3901.71 of the Revised Code, a health	11
benefit plan issued, renewed, or modified in this state shall	12
cover biomarker testing, subject to division (C) of this	13
section, for any of the following purposes:	14
(1) Diagnosis;	15
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(2) Treatment and appropriate management of a disease or	16

condition;	17
(3) Ongoing monitoring of a disease or condition.	18
(C) A health benefit plan shall cover biomarker testing	19
for the purposes included in division (B) of this section when	20
the test is supported by medical and scientific evidence,	21
including any of the following:	22
(1) Labeled indications for a United States food and drug	23
administration approved or cleared test, or indicated tests for	24
a drug approved by the United States food and drug	25
administration;	26
(2) National coverage determinations made by the United	27
States centers for medicare and medicaid services;	28
(3) Medicare administrative contractor local coverage	29
determinations;	30
(4) Nationally recognized clinical practice guidelines;	31
<u>(5) Consensus statements.</u>	32
(D) A health plan issuer shall ensure coverage as required	33
in division (B) of this section in a manner that limits	34
disruptions in care, including the need for multiple biopsies or	35
biospecimen samples.	36
(E) Any appeal of a biomarker testing coverage	37
determination shall be handled in accordance with the health	38
plan issuer's appeal policy and any other relevant provision of	39
law, including section 1751.82 or Chapter 3922. of the Revised	40
Code. The appeal process shall be made readily accessible to all	41
participating providers and recipients in writing and online.	42
Sec. 5164.13. (A) As used in this section:	43

Page 2

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(1) "Biomarker" means a characteristic that is objectively	44
measured and evaluated as an indicator of normal biological	45
processes, pathogenic processes, or pharmacologic responses to	46
specific therapeutic intervention, and includes, but is not	47
limited to, gene mutations or protein expressions.	48
(2) "Biomarker testing" means the analysis of tissue,	49
blood, or another biospecimen for the presence of a biomarker,	50
and includes, but is not limited to, single-analyte tests,	51
multiplex panel tests, and whole genome sequencing.	52
indicipies paner lests, and whole genome sequencing.	52
(3) "Consensus statements" are statements developed by an	53
independent, multidisciplinary panel of experts utilizing a	54
transparent methodology and reporting structure and with a	55
conflict of interest policy.	56
(4) "Nationally recognized clinical practice guidelines"	57
are evidence-based clinical practice guidelines developed by	58
independent organizations or medical professional societies	59
utilizing a transparent methodology and reporting structure and	60
with a conflict of interest policy.	61
(B) The medicaid program shall cover biomarker testing,	62
subject to division (C) of this section, for any of the	63
following purposes:	64
(1) Diagnosis;	65
(2) Treatment and appropriate management of a disease or	66
<pre>condition;</pre>	67
(3) Ongoing monitoring of a disease or condition.	68
(C) The medicaid program shall cover biomarker testing for	69
the purposes included in division (B) of this section when the	70
test is supported by medical and scientific evidence, including	71

72 any of the following: (1) Labeled indications for a United States food and drug 73 administration approved or cleared test, or indicated tests for 74 a drug approved by the United States food and drug 75 76 administration; (2) National coverage determinations made by the United 77 States centers for medicare and medicaid services; 78 79 (3) Medicare administrative contractor local coverage determinations; 80 (4) Nationally recognized clinical practice guidelines; 81 82 (5) Consensus statements. (D) Any appeal of a biomarker testing coverage policy 83 shall be handled in accordance with section 5160.31 of the 84 Revised Code. The appeal process shall be made readily_ 85 accessible to all participating providers and recipients in 86 writing and online. 87

Page 4