WEST VIRGINIA LEGISLATURE 2024 REGULAR SESSION

ENGROSSED

Committee Substitute

for

House Bill 4753

By Delegates Westfall, Barnhart, Riley, Young,
Hornbuckle, W. Hall, Garcia, Jeffries, Hott, Cannon,
and Akers

[Originating in the Committee on the Judiciary;

Reported on February 21, 2024]

A BILL to amend the code of West Virginia, 1931, by adding thereto a new section designated, §5-16-7h; to amend said code by adding thereto a new section designated §9-5-34; to amend said code by adding thereto a new section designated §33-15-4x; to amend said code by adding thereto a new section designated §33-16-3aa; to amend said code by adding thereto a new section designated §33-24-7y; to amend said code by adding thereto a new section designated §33-25-8v; and to amend said code by adding thereto a new section designated §33-25A-8y, all relating to providing health insurance coverage concerning biomarker testing.

Be it enacted by the Legislature of West Virginia:

CHAPTER 5. GENERAL POWERS AND AUTHORITY OF THE GOVERNOR, SECRETARY OF STATE AND ATTORNEY GENERAL; BOARD OF PUBLIC WORKS; MISCELLANEOUS AGENCIES, COMMISSIONS, OFFICES, PROGRAMS, ETC.

ARTICLE 16. WEST VIRGINIA PUBLIC EMPLOYEES INSURANCE ACT. §5-16-7h. Biomarker testing.

- (a) As used in this section:
- (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;
- (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte

9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole
10	transcriptome sequencing;
11	(3) "Consensus statements" means statements that are:
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent
13	methodology and reporting structure with a conflict of interest policy;
14	(B) Aimed at specific clinical circumstances; and
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of
16	clinical care;
17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The Public Employees Insurance Agency shall provide coverage for biomarker
31	testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing
32	monitoring of a covered person's disease or condition when supported by medical and scientific
33	evidence, including, but not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;

1	§9-5-34. (a) As used in		Biomarker	testing.	
	ARTICLE	5.	MISCELLANEOUS	PROVISIONS.	
		CHAPTE	ER 9. HUMAN SERVIC	ES.	
55	report to the Joint Con	nmittee on Gov	rernment and Finance the cos	t of this change.	
54	(c) One year	following imple	mentation, the Public Emplo	yees Insurance Agency shall	
53	website of the insurer.				
52	pursuant to the provis	ions of this sec	ction. The process shall be m	ade readily accessible on the	
51	accessible, and convenient process to request an exception to a coverage policy provided				
50	(5) The covere	d person and p	prescribing practitioner shall h	nave access to a clear, readily	
19	to prior authorization in accordance with §33-16-3dd.				
18	(4) The Public Employees Insurance Agency may require that biomarker testing be subject				
17	the need for multiple biopsies or biospecimen samples.				
1 6	(3) The coverage shall be provided in a manner that shall limit disruptions in care including				
4 5	testing is appropriate.				
14	screening an individua	l prior to receiv	ing a diagnosis of a disease o	condition for which biomarker	
13	(2) Nothing in	this section sha	all require coverage of bioma	rker testing for the purpose of	
12	guidelines is limited to	the use of drug	gs and tests approved or clea	red by the FDA.	
11	consensus statements	s: <i>Provided</i> , Th	at any treatment provided in a	accordance with such practice	
40	the National Compreh	ensive Cancer	Network or the American Soci	ciety of Clinical Oncology, and	
39	(E) Nationally	recognized clin	ical practice guidelines such	as, but not limited to, those of	
38	Medicare administrativ	ve contractor lo	cal coverage determinations;	<u>or</u>	
37	(D) Centers for Medicare and Medicaid Services national coverage determinations an				
36	(C) Warnings and precautions on FDA-approved drug labels;				
35	(B) Indicated tests for an FDA-approved drug;				

2	(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a
4	specific therapeutic intervention, including known gene-drug interactions for medications being
5	considered for use or already being administered; and includes but is not limited to gene
6	mutations, characteristics of genes and protein expression;
7	(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other
8	biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte
9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole
10	transcriptome sequencing;
11	(3) "Consensus statements" means statements that are:
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent
13	methodology and reporting structure with a conflict of interest policy;
14	(B) Aimed at specific clinical circumstances; and
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of
16	clinical care;
17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The Bureau for Medical Services shall provide coverage for biomarker testing for the
31	purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a
32	covered person's disease or condition when supported by medical and scientific evidence,
33	including, but not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
47	the need for multiple biopsies or biospecimen samples.
48	(4) The Bureau of Medical Services may require that biomarker testing be subject to prior
49	authorization in accordance with §33-16-3dd.
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily
51	accessible, and convenient process to request an exception to a coverage policy provided
52	pursuant to the provisions of this section. The process shall be made readily accessible on the
53	website of the insurer.

54	(c) One year following implementation, the Bureau of Medical Services shall repo	ort to the			
55	Joint Committee on Government and Finance the cost of this	change.			
	CHAPTER 33. INSURANCE.				
	ARTICLE 15. ACCIDENT AND SICKNESS INSUF	RANCE.			
	§33-15-4x. Biomarker	testing.			
1	(a) As used in this section:				
2	(1) "Biomarker": means a characteristic that is objectively measured and evaluate	ed as an			
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic respon	ises to a			
4	specific therapeutic intervention, including known gene-drug interactions for medication	ns being			
5	considered for use or already being administered; and includes but is not limited	to gene			
6	mutations, characteristics of genes and protein expression;				
7	(2) "Biomarker testing": means the analysis of a patient's tissue, blood,	or other			
8	biospecimen for the presence of a biomarker; and includes but is not limited to single	_			
		•			
9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole				
10	transcriptome sequencing;				
11	(3) "Consensus statements" means statements that are:				
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a train	<u>nsparent</u>			
13	methodology and reporting structure with a conflict of interest policy;				
14	(B) Aimed at specific clinical circumstances; and				
15	(C) Based on the best available evidence for the purpose of optimizing the outc	comes of			
16	clinical care;				
17	(4) "FDA" means the United States Food and Drug Administration; and				
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based	d clinical			
19	practice guidelines that:				
10	practice galacinics triat.				

20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
11	consensus statements: Provided, That any treatment provided in accordance with such practice
12	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
14	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
15	testing is appropriate.

46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including						
47	the need for multiple biopsies or biospecimen samples.						
48	(4) The health insurers may require that biomarker testing be subject to prior authorization						
49	in accordance	e with §	33-16-3dd.				
50	<u>(5) Th</u>	e cover	ed person an	d prescribing pra	ctitioner s	hall have access	to a clear, readily
51	accessible, a	nd con	venient proce	ess to request a	ın exception	on to a coverag	e policy provided
52	pursuant to the	ne provi	sions of this s	section. The prod	ess shall	be made readily	accessible on the
53	website		O	•	ti	ne	insurer.
	ARTICLE	16.	GROUP	ACCIDENT	AND	SICKNESS	INSURANCE.
	<u>§33-16-3aa.</u>			Bioma	ırker		testing.
1	<u>(a) As</u>	used ir	this section:				
2	<u>(1) "Bi</u>	<u>iomarke</u>	er": means a c	naracteristic that	is objectiv	ely measured an	d evaluated as an
3	indicator of n	ormal b	iologic proces	ses, pathogenic	processes	s, or pharmacolog	jic responses to a
4	specific thera	peutic i	ntervention, in	ncluding known	gene-drug	interactions for r	medications being
5	considered for use or already being administered; and includes but is not limited to gene						
6	mutations, characteristics of genes and protein expression;						
7	(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other						
8	biospecimen	for the	presence of a	a biomarker; and	l includes	but is not limited	l to single-analyte
9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole						
10	transcriptome sequencing;						
11	(3) "Consensus statements" means statements that are:						
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent						
13	methodology and reporting structure with a conflict of interest policy;						
14	(B) Aimed at specific clinical circumstances; and						
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of						
16	clinical care;						

17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
11	consensus statements: Provided, That any treatment provided in accordance with such practice
12	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of			
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker			
45	testing is appropriate.			
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including			
47	the need for multiple biopsies or biospecimen samples.			
48	(4) The health insurers may require that biomarker testing be subject to prior authorization			
49	in accordance with §33-16-3dd.			
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily			
51	accessible, and convenient process to request an exception to a coverage policy provided			
52	pursuant to the provisions of this section. The process shall be made readily accessible on the			
53	website of the insurer.			
	ARTICLE 24. HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE			
	CORPORATIONS, DENTAL SERVICE CORPORATIONS, AND HEALTH			
	CORPORATIONS, DENTAL SERVICE CORPORATIONS, AND HEALTH SERVICE CORPORATIONS.			
1	SERVICE CORPORATIONS.			
1 2	SERVICE CORPORATIONS. §33-24-7y. Biomarker testing.			
	SERVICE CORPORATIONS. §33-24-7y. Biomarker testing. (a) As used in this section:			
2	SERVICE CORPORATIONS. §33-24-7y. Biomarker testing. (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an			
2	SERVICE Salary. Biomarker (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a			
2 3 4	SERVICE Salary. Biomarker testing. (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being			
2 3 4 5	SERVICE Salary. Biomarker (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene			
2 3 4 5 6	SERVICE Biomarker (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;			
2 3 4 5 6 7	SERVICE Signary Biomarker testing. (a) As used in this section: (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression; (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other			

11	(3) "Consensus statements" means statements that are:
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent
13	methodology and reporting structure with a conflict of interest policy;
14	(B) Aimed at specific clinical circumstances; and
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of
16	clinical care;
17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;

37	(D) Centers for Medicare and Medicaid Services national coverage determinations and					
38	Medicare administrative contractor local coverage determinations; or					
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of					
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and					
41	consensus state	ements: Provide	ed, That any treatm	nent provided in acco	rdance with such practice	
42	guidelines is lim	ited to the use o	of drugs and tests	approved or cleared b	by the FDA.	
43	(2) Noth	ing in this section	on shall require co	verage of biomarker	testing for the purpose of	
44	screening an inc	dividual prior to r	eceiving a diagnos	is of a disease or con	dition for which biomarker	
45	testing is approp	oriate.				
46	(3) The c	coverage shall b	e provided in a ma	nner that shall limit di	sruptions in care including	
47	the need for mu	<u>ltiple biopsies o</u>	r biospecimen san	nples.		
48	<u>(4) The h</u>	nealth insurers r	may require that bid	omarker testing be sul	bject to prior authorization	
49	in accordance w	vith §33-16-3dd.	<u>.</u>			
50	(5) The	covered person	and prescribing p	ractitioner shall have	access to a clear, readily	
51	accessible, and	convenient pr	ocess to request	an exception to a	coverage policy provided	
52	pursuant to the	provisions of th	nis section. The pro	ocess shall be made	readily accessible on the	
53	website		of	the	insurer.	
	ARTICLE	25.	HEALTH	CARE	CORPORATIONS.	
	§33-25-8v.		Biom	arker	testing.	
1	<u>(a) As us</u>	sed in this section	on:			
2	(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an					
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a					
4	specific therapeutic intervention, including known gene-drug interactions for medications being					
5	considered for use or already being administered; and includes but is not limited to gene					
6	mutations, characteristics of genes and protein expression;					

7	(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other
8	biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte
9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole
10	transcriptome sequencing;
11	(3) "Consensus statements" means statements that are:
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent
13	methodology and reporting structure with a conflict of interest policy;
14	(B) Aimed at specific clinical circumstances; and
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of
16	clinical care;
17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
23	(B) Establish standards of care informed by:
24	(i) A systematic review of evidence; and
25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered

1	§33-25A-8y. Biomarker testing. (a) As used in this section:
	ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT.
3	website of the insurer.
52	pursuant to the provisions of this section. The process shall be made readily accessible on the
51	accessible, and convenient process to request an exception to a coverage policy provided
0	(5) The covered person and prescribing practitioner shall have access to a clear, readily
9	in accordance with §33-16-3dd.
8	(4) The health insurers may require that biomarker testing be subject to prior authorization
7	the need for multiple biopsies or biospecimen samples.
6	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
5	testing is appropriate.
4	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
3	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
2	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
1	consensus statements: Provided, That any treatment provided in accordance with such practice
0	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
9	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
88	Medicare administrative contractor local coverage determinations; or
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
86	(C) Warnings and precautions on FDA-approved drug labels;
35	(B) Indicated tests for an FDA-approved drug;
84	(A) Labeled indications for a test approved or cleared by the FDA;
3	not limited to:
32	person's disease or condition when supported by medical and scientific evidence, including, but

2	(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a
4	specific therapeutic intervention, including known gene-drug interactions for medications being
5	considered for use or already being administered; and includes but is not limited to gene
6	mutations, characteristics of genes and protein expression;
7	(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other
8	biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte
9	tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole
10	transcriptome sequencing;
11	(3) "Consensus statements" means statements that are:
12	(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent
13	methodology and reporting structure with a conflict of interest policy;
14	(B) Aimed at specific clinical circumstances; and
15	(C) Based on the best available evidence for the purpose of optimizing the outcomes of
16	clinical care;
17	(4) "FDA" means the United States Food and Drug Administration; and
18	(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical
19	practice guidelines that:
20	(A) Are developed by an independent organization or medical professional society utilizing
21	a transparent methodology and reporting structure with a conflict of interest policy and include
22	recommendations intended to optimize care;
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24	(i) A systematic review of evidence; and
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26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
47	the need for multiple biopsies or biospecimen samples.
48	(4) The health insurers may require that biomarker testing be subject to prior authorization
49	in accordance with §33-16-3dd.
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily
51	accessible, and convenient process to request an exception to a coverage policy provided
52	pursuant to the provisions of this section. The process shall be made readily accessible on the
53	website of the insurer.