

Senate Engrossed

~~biomarker testing; insurance coverage; definitions~~  
(now: insurance coverage; biomarker testing)

State of Arizona  
Senate  
Fifty-sixth Legislature  
First Regular Session  
2023

# SENATE BILL 1052

AN ACT

AMENDING SECTIONS 20-1376.10 AND 20-1406.10, ARIZONA REVISED STATUTES;  
RELATING TO BIOMARKER TESTING.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Section 20-1376.10, Arizona Revised Statutes, is amended  
3 to read:

4 20-1376.10. Biomarker testing; coverage; definitions

5 A. A disability insurer that issues, amends, delivers or renews a  
6 policy on or after January 1, 2023 shall provide coverage for biomarker  
7 testing.

8 B. A policy shall cover biomarker testing for the purposes of  
9 diagnosis, treatment, appropriate management or ongoing monitoring of an  
10 insured's disease or condition to guide treatment decisions when the test  
11 provides clinical utility as demonstrated by medical and scientific  
12 evidence, including any of the following:

13 1. Labeled indications for tests that are approved or cleared by  
14 the United States food and drug administration or indicated tests for a  
15 drug that is approved by the United States food and drug administration.

16 2. Centers for medicare and medicaid services national coverage  
17 determinations or medicare administrative contractor local coverage  
18 determinations.

19 3. Nationally recognized clinical practice guidelines and consensus  
20 statements.

21 C. A disability insurer must ensure that coverage is provided in a  
22 manner that limits disruptions in care, including the need for multiple  
23 biopsies or biospecimen samples.

24 D. The insured and prescribing practitioner must have access to a  
25 clear, readily accessible and convenient process to request an exception  
26 to a coverage policy of a disability insurer. The process shall be  
27 readily accessible on the disability insurer's website. This subsection  
28 does not require a separate process if the disability insurer's existing  
29 process complies with this subsection.

30 E. A POLICY THAT IS ISSUED OR RENEWED BY A DISABILITY INSURER DOES  
31 NOT INCLUDE A POLICY THAT PROVIDES LIMITED BENEFIT COVERAGE AS DEFINED IN  
32 SECTION 20-1137.

33 ~~F.~~ F. For the purposes of this section:

34 1. "Biomarker":

35 (a) Means a characteristic that is objectively measured and  
36 evaluated as an indicator of normal biological processes, pathogenic  
37 processes or pharmacologic responses to a specific therapeutic  
38 intervention.

39 (b) Includes gene mutations or protein expression.

40 2. "Biomarker testing":

41 (a) Means the analysis of a patient's tissue, blood or other  
42 biospecimen for the presence of a biomarker.

43 (b) Includes single-analyte tests, multiplex panel tests and whole  
44 genome sequencing.

1           3. "Clinical utility" means the test result provides information  
2 that is used in the formulation of a treatment or monitoring strategy that  
3 informs a patient's outcome and impacts the clinical decision. The most  
4 appropriate test may include both information that is actionable and some  
5 information that cannot be immediately used in the formulation of a  
6 clinical decision.

7           4. "Consensus statements" means statements that ARE ALL OF THE  
8 FOLLOWING:

9           (a) ~~Are~~ Developed by an independent, multidisciplinary panel of  
10 experts using a transparent methodology and reporting structure that  
11 includes a conflict of interest policy.

12           (b) ~~Are~~ Based on the best available evidence for the purpose of  
13 optimizing clinical care outcomes.

14           (c) ~~Are~~ Aimed at specific clinical circumstances.

15           5. "Nationally recognized clinical practice guidelines" means  
16 evidence-based clinical practice guidelines that both:

17           (a) Are developed by independent organizations or medical  
18 professional societies using a transparent methodology and reporting  
19 structure and a conflict of interest policy.

20           (b) Establish standards of care that are informed by a systematic  
21 review of evidence and an assessment of the benefits and costs of  
22 alternative care options that includes recommendations intended to  
23 optimize patient care.

24           Sec. 2. Section 20-1406.10, Arizona Revised Statutes, is amended to  
25 read:

26           20-1406.10. Biomarker testing; coverage; definitions

27           A. A group or blanket disability insurer that issues, amends,  
28 delivers or renews a policy on or after January 1, 2023 shall provide  
29 coverage for biomarker testing.

30           B. A policy shall cover biomarker testing for the purposes of  
31 diagnosis, treatment, appropriate management or ongoing monitoring of an  
32 insured's disease or condition to guide treatment decisions when the test  
33 provides clinical utility as demonstrated by medical and scientific  
34 evidence, including any of the following:

35           1. Labeled indications for tests that are approved or cleared by  
36 the United States food and drug administration or indicated tests for a  
37 drug that is approved by the United States food and drug administration.

38           2. Centers for medicare and medicaid services national coverage  
39 determinations or medicare administrative contractor local coverage  
40 determinations.

41           3. Nationally recognized clinical practice guidelines and consensus  
42 statements.

43           C. A group or blanket disability insurer must ensure coverage is  
44 provided in a manner that limits disruptions in care, including the need  
45 for multiple biopsies or biospecimen samples.

1 D. The insured and prescribing practitioner must have access to a  
2 clear, readily accessible and convenient process to request an exception  
3 to a coverage policy of a group or blanket disability insurer. The  
4 process shall be readily accessible on ~~a~~ THE group or blanket disability  
5 insurer's website. This subsection does not require a separate process if  
6 the group or blanket disability insurer's existing process complies with  
7 this subsection.

8 E. A POLICY THAT IS ISSUED OR RENEWED BY A GROUP OR BLANKET  
9 DISABILITY INSURER DOES NOT INCLUDE A POLICY THAT PROVIDES A LIMITED  
10 BENEFIT COVERAGE AS DEFINED IN SECTION 20-1137.

11 ~~E.~~ F. For the purposes of this section:

12 1. "Biomarker":

13 (a) Means a characteristic that is objectively measured and  
14 evaluated as an indicator of normal biological processes, pathogenic  
15 processes or pharmacologic responses to a specific therapeutic  
16 intervention.

17 (b) Includes gene mutations or protein expression.

18 2. "Biomarker testing":

19 (a) Means the analysis of a patient's tissue, blood or other  
20 biospecimen for the presence of a biomarker.

21 (b) Includes single-analyte tests, multiplex panel tests and whole  
22 genome sequencing.

23 3. "Clinical utility" means the test result provides information  
24 that is used in the formulation of a treatment or monitoring strategy that  
25 informs a patient's outcome and impacts the clinical decision. The most  
26 appropriate test may include both information that is actionable and some  
27 information that cannot be immediately used in the formulation of a  
28 clinical decision.

29 4. "Consensus statements" means statements that ARE ALL OF THE  
30 FOLLOWING:

31 (a) ~~Are~~ Developed by an independent, multidisciplinary panel of  
32 experts using a transparent methodology and reporting structure that  
33 includes a conflict of interest policy.

34 (b) ~~Are~~ Based on the best available evidence for the purpose of  
35 optimizing clinical care outcomes.

36 (c) ~~Are~~ Aimed at specific clinical circumstances.

37 5. "Nationally recognized clinical practice guidelines" means  
38 evidence-based clinical practice guidelines that both:

39 (a) Are developed by independent organizations or medical  
40 professional societies using a transparent methodology and reporting  
41 structure and a conflict of interest policy.

42 (b) Establish standards of care that are informed by a systematic  
43 review of evidence and an assessment of the benefits and costs of  
44 alternative care options that includes recommendations intended to  
45 optimize patient care.