

Senate Engrossed

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

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

CHAPTER 29
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
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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.

APPROVED BY THE GOVERNOR APRIL 11, 2023.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 11, 2023.