

REFERENCE TITLE: biomarker testing; insurance coverage; definitions

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

SB 1052

Introduced by
Senator Shope

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. For the purposes of this section:

31 1. "Biomarker":

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

36 (b) Includes gene mutations or protein expression.

37 2. "Biomarker testing":

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

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

42 3. "Clinical utility" means the test result provides information
43 that is used in the formulation of a treatment or monitoring strategy that
44 informs a patient's outcome and impacts the clinical decision. The most
45 appropriate test may include both information that is actionable and some

1 information that cannot be immediately used in the formulation of a
2 clinical decision.

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

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

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

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

11 5. "Nationally recognized clinical practice guidelines" means
12 evidence-based clinical practice guidelines that both:

13 (a) Are developed by independent organizations or medical
14 professional societies using a transparent methodology and reporting
15 structure and a conflict of interest policy.

16 (b) Establish standards of care that are informed by a systematic
17 review of evidence and an assessment of the benefits and costs of
18 alternative care options that includes recommendations intended to
19 optimize patient care.

20 6. DISABILITY INSURER DOES NOT INCLUDE LIMITED BENEFIT COVERAGE AS
21 DEFINED IN SECTION 20-1137.

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

24 20-1406.10. Biomarker testing; coverage; definitions

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

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

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

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

39 3. Nationally recognized clinical practice guidelines and consensus
40 statements.

41 C. A group or blanket disability insurer must ensure coverage is
42 provided in a manner that limits disruptions in care, including the need
43 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. For the purposes of this section:

9 1. "Biomarker":

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

14 (b) Includes gene mutations or protein expression.

15 2. "Biomarker testing":

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

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

20 3. "Clinical utility" means the test result provides information
21 that is used in the formulation of a treatment or monitoring strategy that
22 informs a patient's outcome and impacts the clinical decision. The most
23 appropriate test may include both information that is actionable and some
24 information that cannot be immediately used in the formulation of a
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39 (b) Establish standards of care that are informed by a systematic
40 review of evidence and an assessment of the benefits and costs of
41 alternative care options that includes recommendations intended to
42 optimize patient care.

43 6. GROUP OR BLANKET DISABILITY INSURER DOES NOT INCLUDE LIMITED
44 BENEFIT COVERAGE AS DEFINED IN SECTION 20-1137.